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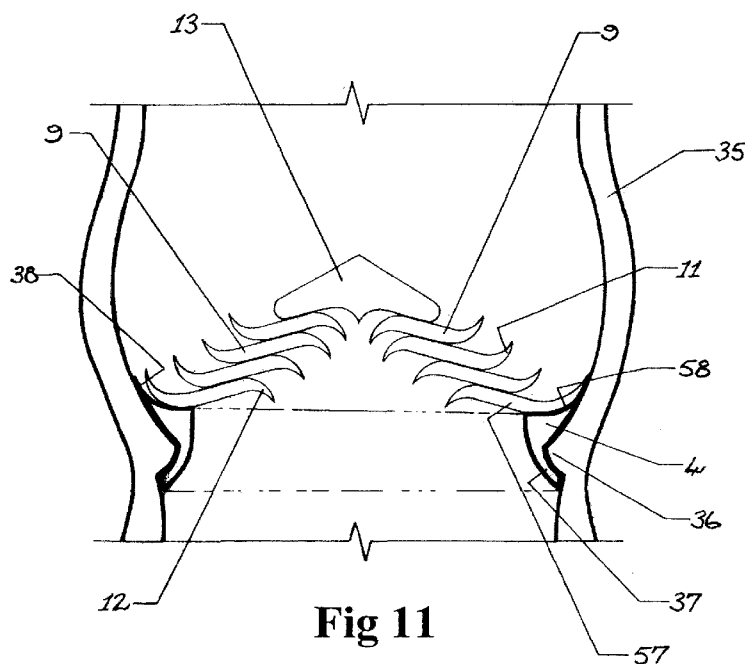
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(54) Title: PROSTHETIC VALVE



(57) Abstract: A prosthesis to replace a venous or cardiac valve comprising a valving element in the form of a plurality of spirally-arranged, partially overlapping and facially abutting layers, said valving element being made in a single piece from a thin, elastic material, the end of its outer turn being fixed to an annular supporting ring and the end of its final turn terminating in a capping piece which acts as a central closure of said layers; in their collapsed, abutting state, said partially overlapping layers acting to provide a complete obstruction to flow in one direction but, when pressure is applied to them from the counter direction, lifting and elastically separating in a mode similar to that of the coils of a very light spring; opening of said valve involving only a small torsional distortion distributed more or less equally throughout the whole length of said valving element.

PROSTHETIC VALVE

This invention relates to prosthetic valves for the replacement of native cardiac valves or valves in venous vessels where those valves are congenitally defective, have been damaged by disease or have deteriorated with age. In particular, it relates to
5 prosthetic valves for the replacement of defective, damaged or deteriorated valves in smaller vessels, such valves having hitherto been difficult to replace with prostheses.

In the human body, it is not uncommon for the native cardiac valves and valves in venous vessels to be congenitally defective, to be damaged by disease or to deteriorate with age. In the heart, for example, valvular disease is common, with any of the four
10 cardiac valves becoming stenotic (narrowed or restricted in flow) or developing insufficiency (leakage or backflow). Such conditions may be congenital, may be caused by disease, may result from a progressive deterioration or be the result of drug or radiation treatment. While techniques exist to repair or restore a damaged or deteriorated cardiac valve, where valve failure compromises haemodynamic efficiency
15 to a degree that is life threatening, one method of treatment is to implant a replacement. The replacement may be a homograft from a human donor, a xenograft in the form of a porcine valve, a bioprosthetic valve incorporating biological tissue or a mechanical prosthetic valve. Occasionally, as in the Ross Procedure, a native valve may be transposed in a heart. Replacement valves in which the valvular leaves are of biological
20 origin tend to be less thrombogenic than purely mechanical valves, but are not as durable and may require replacement sooner. In all cases in which purely mechanical prosthetic valves are implanted, anticoagulants must be administered on a continuing basis to prevent the formation of thromboses. Prosthetic heart valves take a variety of forms. In bioprosthetic valves, the valvular leaves of a porcine valve are attached to a supporting
25 structure having a fixation band or sewing ring or, alternatively, bovine or equine pericardial material is formed into a multi-leaf valve approximating the shape of the native valve and attached to a fixation band or sewing ring. In the conventional open-heart, surgical technique, the native valve is excised and the fixation band or sewing ring is sutured into place to install the prosthetic valve. Recent innovation includes the
30 development of a multi-leaf valve made from a synthetic material. Bioprosthetic valves have also been developed in which a multi-leaf valve is supported in a balloon-expandable stent. Instead of implantation through conventional, open-heart surgical

techniques with cardio-pulmonary bypass, these valves are positioned in a collapsed state within a diseased valve of a beating heart using an endovascular or transapical approach and the stent then expanded to secure the valve in place and restore it to its functional shape. Purely mechanical prosthetic valves are conventionally based upon a
5 fixation band or sewing ring and comprise a variety of valving elements or occluders which seal to seats, including caged ball, tilting disk (pivoting circular element) and bi-leaflet (pivoting, semi-circular elements). In a more recent form of prosthetic valve, a biochemically-inert, synthetic polymer-based material is used to create flexible, tri-leaflet valves. Through the use of modern materials, mechanical prosthetic valves have
10 been made very reliable and have long service lives of 20 to 30 years. Of the various prosthetic heart valves, bi-leaflet valves are vulnerable to backflow and so cannot be considered as ideal. Bi-leaflet valves do, however, provide a much more natural blood flow than caged-ball or tilting-disc valves. The advantages of bi-leaflet valves is that they offer a greater effective opening area (2.4 to 3.2 square centimetres compared with
15 1.5 to 2.1 square centimetres for the single-leaflet valves) and are well tolerated by the body. They are the least thrombogenic prosthetic valve type, with smaller dosages of anti-coagulants being required by recipients. In mechanical prosthetic heart valves, struts and occluders are made from either pyrolytic carbon or titanium coated with pyrolytic carbon, and the sewing ring cuff is Teflon, polyester or dacron. In operation,
20 the major load arises from transvalvular pressure generated at and after valve closure and, where structural failure occurs, it is normally the result of occluder impact on the failed component. Impact wear and friction wear cause a loss of material in mechanical prosthetic heart valves. Impact wear normally occurs in the hinge regions of bi-leaflet valves, between occluder and ring in tilting-disk valves, and between the ball and cage in
25 caged-ball valves. The ideal prosthetic heart valve has no high stress concentrations in its components. Frictional wear occurs between the occluder and strut in tilting-disk valves, and between the leaflet pivots and hinge cavities in bi-leaflet valves. Metal components may be susceptible to fatigue failure resulting from the polycrystalline characteristic of metals, but is avoided with the use of pyrolytic carbon. Thrombus
30 formation results from high shear effects in the bloodstream created by the particular prosthetic valve design. It can be mitigated by having a minimal pressure drop across the valve with minimal flow turbulence and minimal flow separation and flow

stagnation in the vicinity of the valve. The ideal prosthetic heart valve should have only a small regurgitation volume. Regurgitation is the sum of retrograde flow during the closing motion of a prosthetic heart valve and leakage flow after closure. It is directly proportional to valve size and is also dependent on valve type. Typically, caged-ball valves have a low amount of regurgitation as there is very little leakage. Tilting-disk and bi-leaflet valves are comparable, with the bi-leaflet valves having a slightly larger regurgitation volume. Bio-prosthetic heart valves are superior to mechanical valves in that they have virtually no regurgitation volume. Cavitation may also cause deterioration of mechanical heart valve components, with deleterious effects created at the edges of the annular jet in caged-ball valves, in narrow regions at the edges of the major orifice jet in tilting-disk valves, and in regions immediately distal to the valve leaflets in bi-leaflet valves. Cavitation can result from pressure oscillations, flow deceleration, tip vortices, streamline contraction, and squeeze jets. Squeeze jets are the most common cause of cavitation in mechanical prosthetic heart valves and are formed during valve closure when the blood between the occluder and valve housing is expelled in the form of a high velocity jet. This in turn creates intense vortices with very low pressures that may lead to cavitation. All forms of mechanical prosthetic heart valve are vulnerable to thrombus formation due to high shear stress, stagnation, and flow separation. The caged-ball designs experience high stresses at the walls that can damage cells, as well as flow separation due to high-velocity reverse flow surrounded by stagnant flow. Tilting-disk valves have flow separation behind the valve struts and disk as a result of a combination of high velocity and stagnant flows. Bi-leaflet models have high stresses during forward and leakage flows as well as adjacent stagnant flow in the hinge area. The hinge area is the most critical part of bi-leaflet valves and the location of most thrombus formation. Blood damage results from valves in both the mitral and aortic positions. High stresses during leakage flow in aortal valves result from higher transvalvular pressures, and high stresses occur during forward flow for mitral valves. Valvular thrombosis is most common in mitral prosthetics, with the caged-ball valve having a lower risk of thrombus formation. The bi-leaflet valve is more tolerant of thrombus formation than the tilting-disc model, as hinge blockage may leave at least one leaflet still functioning. Bioprosthetic valves are less prone to thrombus formation or to cause haemolytic anaemia as a result of haemolysis of the red blood cells as they pass through the valve.

Within the body, approximately 75% of circulating blood is moving through the venous vessels. Thus, an understanding of the mechanisms by which venous return to the heart is accomplished is crucial to understanding the physiology of the vascular system. Phasicity, in the venous system, refers to the ebb and flow that occurs in normal veins in response to respiration. All deep veins normally exhibit phasicity in relation to the two phases of respiration, the way in which blood movement responds to the respirational phases differing according to the part of the body affected and the postural disposition of the body. Respiration has profound effects on venous pressure and flow. During inspiration, for example, the thoracic cavity expands, the diaphragm lowers and the abdomen becomes smaller. The volume of the veins of the thorax increases and the pressure decreases in response to the reduced intrathoracic pressure. In the abdomen, because of the descent of the diaphragm, the pressure increases, increased abdominal pressure decreasing pressure gradients between peripheral veins in the lower extremities and the abdomen, thereby reducing flow in the vessels. During expiration, the thoracic cavity decreases, the diaphragm elevates and the abdomen expands. The volume of the veins of the thorax decreases and the pressure increases. In the abdomen, because of the elevation of the diaphragm, the pressure decreases, decreased abdominal pressure increasing pressure gradients between the peripheral veins in the lower extremities and the abdomen, thereby increasing flow to the vessels. In summary, during inspiration, blood flow out of the legs slows or stops. During expiration, flow resumes.

Hydrostatic pressure is the pressure exerted by fluid within a closed system. In the body, hydrostatic pressure varies with position. When the body is supine, there is virtually no hydrostatic pressure in the legs, as they are at the same level as the right atrium of the heart, which has a pressure of zero. Gravity normally exerts significant effects on venous return because of our upright posture. As body posture is changed from supine to standing, gravity acts upon the vascular volume, such that blood tends to accumulate in the lower extremities. Because venous compliance is high, most of the blood volume shift occurs in the veins. When venous valves are working correctly, every movement of the leg causes blood to be pumped inward and upward past a series of valves in the vessels. This is known as the musculo-venous pump mechanism. During walking, the pressure in the venous system of the lower leg

progressively falls. Upon standing, arterial inflow begins to fill the leg veins slowly and the only source of venous pressure is the hydrostatic pressure of a column of blood as high as the nearest competent valve. After prolonged standing, the veins are completely filled and all the venous valves float open. At this time, high hydrostatic
5 venous pressure results from the unbroken column of fluid that extends from the head to the foot. Failed or incompetent valves then cause the column of standing blood in the veins to remain high even when during walking.

Venous valves play a very important role in the function of venous return, especially in the lower extremities. They are irregularly located along the veins, but
10 are always found at the junctions of tributaries with main venous channels or where two large veins join. Venous valves are usually bicuspid and occasionally tricuspid. In the leg, some veins have fewer valves than others. The deep system has more valves than the superficial. Venous valves direct flow, keeping the blood moving back toward the heart in both the deep and the superficial veins. In the perforating veins,
15 which pass through muscles, the valves direct the flow from the superficial veins to the deep veins, the venous valves, if functioning normally, preventing reflux. When the deep vein valves are incompetent, blood squeezed upward by muscular contraction simply flows back down during muscle relaxation. Additionally, blood is often forced back down the veins toward the foot by muscle contraction, dramatically increasing
20 distal venous pressure and venous hypertension. The condition is exacerbated if the perforating vein valves are insufficient as well. In the extremities, the deep veins are surrounded by muscles. As the muscles contract, they compress the veins within them. Muscles do not remain permanently contracted and, to function, they must alternately contract and relax, thereby propelling the blood up the leg. In the venous
25 system, it is the interaction of the venous valves and the muscle pump that keep venous blood moving, and moving in the right direction. When these two elements are working properly, the veins in the lower extremities can empty so effectively that emptying is actually complete. A standing person may have an ankle venous pressure of approximately 90 mm Hg. Upon exercising the leg muscles, if the musculovenous
30 pump mechanism is functioning properly, the ankle venous pressure will fall to below 30 mm Hg and, in some case, as low as 1 mm Hg.

While incompetence or absence of valves may be congenital, valvular

deterioration is characteristically a progressive process. Thrombotic deposits may cause valve leaflets to adhere to the vessel wall or, in forming on leaflets, cause a permanent fibrous deterioration or scarring. Leakage from the resultant incompetent valve causes increased hydrostatic pressure on the vessel immediately below closed by the next succeeding valve. The resultant dilatation of the vessel in the region of that valve below causes enlargement of supporting tissue around the valve with separation of the valve leaflets and leakage, thereby imposing increased hydrostatic pressure on the vessel and valve below, so establishing a progressive, cascading process of deterioration.

10 A common valve-related disorder is chronic venous insufficiency (CVI), an advanced stage of venous disease caused either by superficial or deep venous pathology. CVI results from dysfunctional valves that reduce venous return and thereby increase venous pressure in the legs. As a result of valvular incompetence, venous blood flow is bi-directional, resulting in inefficient venous outflow. The net effect of this is the imposition upon the leg veins of the full weight of the venous blood column from the right atrium down. As a result, a very high venous pressure is exerted at the ankle and the venules become the final pathway for the highest venous pressure. Chronic venous insufficiency can be divided into primary and secondary varicose veins. Primary varicose veins are those which only involve the superficial system. Secondary varicose veins are usually attributable to previous deep venous thrombosis (DVT), which has caused damage to the valves of the deep veins and perforators. One popular explanation for the production of incompetent venous valves is an inherent structural weakness of the veins themselves, which is frequently hereditary. Haemodynamic factors play a significant role in producing primary varicosities. The most important of these is the high hydrostatic pressure to which the veins to the lower extremities are subjected as a result of the patient standing. Other factors include heavy muscular work, such as lifting, repeated straining at stool, pregnancy, and pelvic tumours, all of which increase intra-abdominal tension. Secondary varicose veins, the most serious of all venous disorders, occur when the deep venous system is obstructed and the valvular mechanisms are destroyed or rendered incompetent. This is thought to occur when there has been an episode of deep venous thrombosis leading to two problems – obstruction of the deep veins and

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subsequent destruction of the venous valves. When venous obstruction occurs, the venous blood is forced to follow alternate pathways to reach the heart. One way is to force the opening of new pathways (co-laterals), or to use the superficial system as the alternate pathway. However, the flow in the communicating (perforating) veins is now reversed, from deep to superficial. Venous hypertension (high pressure) results in the formation of oedema fluid, as well as extravasation of red blood cells and large protein molecules that leak out from capillaries. Initially, soft pitting oedema is present at the ankle, but over a period of time the skin becomes thickened and acquires a woody feeling. The haemoglobin from these cells is broken down to haem pigment, which is taken up by tissue macrophages, resulting in the brown skin pigment associated with chronic insufficiency. Venous hypertension also results in the production of a fibrin cuff around capillaries, inhibiting oxygen diffusion to adjacent tissues and thereby causing local tissue atrophy and skin ulceration.

When the valves in the veins of the lower extremities become incompetent, there is regurgitation of blood in the superficial venous system which produces varicosities. Depending upon the site of involvement, this reflux takes place either through the saphenofemoral junction or through communication of perforator vessels. As a result of the marked distention of the superficial veins and the poor support they possess, these vessels enlarge and become tortuous, in the process of which the valves locally also become incompetent. If the perforating veins valves are incompetent as well, increased pressure is transmitted through perforating veins to the capillary bed' this in turn resulting in exudation of protein-rich fluid and red blood cells into the subcutaneous tissues. Degenerated red blood cells and organised protein-rich exudate produce induration and hyperpigmentation. It is suggested that fibrin is deposited around capillaries as a result of increased capillary permeability. These deposits prevent diffusion of oxygen to adjacent cells, causing limitation in healing capability and or cutaneous atrophy so that ulceration may result from even minor injuries. Clinical consequences of chronic venous insufficiency may be as simple as itching, aching of a limb or eczema or, more seriously, intractable superficial, arterial or venous ulceration.

Venous valve incompetence is treated conservatively with manual compression, lymphatic massage therapy, skin lubrication, sequential compression

pump, ankle pump, compression stockings, blood pressure medication, frequent periods of rest while elevating the legs above the heart level and raising the foot of the bed during sleep. Surgical treatments for removal of varicose veins (including the older Linton procedure and newer sub-fascial endoscopic perforator vein procedure) have been employed for many years. Valve repair and valve transposition procedures have been developed and surgical techniques to improve hemodynamic efficiency are being pursued. Valve repair techniques involve opening a vessel and suturing valve leaflets to retain them in a functional position. Alternatively, sutures are inserted into a dilated vessel from its exterior to narrow it and draw valve leaflets together into a functional position. In another alternative, a cuff is installed around a dilated vessel and tightened to achieve the same effect.

Most subjects with CVI are middle-aged or older women, often with a family history of venous insufficiency. Approximately 2 to 5% of American people (seven million in 2008) are acknowledged as suffering from CVI to some degree with some 600,000 new cases being diagnosed annually. Ulcer healing rates can be poor with up to 50% of venous ulcers open and unhealed for 9 months. In the UK, leg ulcer treatment accounts for 1.3% of the total healthcare budget and up to 90% are treated in the community. In the United States, venous ulcers have been estimated to cause the loss of two million working days and to incur treatment costs of approximately \$3 billion per year (Bergan JJ et al, 2006). DVT may result in the development of pulmonary emboli, leading to an annual mortality rate in the USA of approximately one per cent of sufferers.

Another example of a valve-related disorder is varicoceles resulting from valvular failure or incompetence in the male internal spermatic vein. Loss of valvular efficiency compromises the musculo-venous pump mechanism that drains venous blood from the testicular region. While varicoceles often develop at puberty, they are primarily the result of progressive valvular deterioration with age. The result is an elevated hydrostatic pressure some six-fold that of normal pressure in the venous drainage of the male reproductive system manifesting as varicocele, a varicose condition of the pampiniform venous plexus. Resulting in reduced oxygen supplies to the testicular tissue and, as a result, deteriorated sperm production, varicocele is acknowledged as being the principal cause of male infertility. Elevated venous blood pressure

propagates to all interconnected vessels and, in the case of varicocele, leads to a unique biological phenomenon: venous blood flows retrograde from the higher pressure in the testicular venous drainage system to the lower pressure in the prostatic drainage system directly to the prostate. According to Gat et al¹, free testosterone
5 levels in this retrograde blood flow are markedly elevated, with a concentration of some 130-fold above normal serum level. Consequently, the prostate is exposed to increased venous pressure causing hypertrophy; and an elevated concentration of free testosterone causing benign prostatic hyperplasia. Restoration of normal pressure in the venous drainage and elimination of the back-flow of blood from the testicular to
10 the prostate drainage system produces a rapid reduction in prostate volume and a regression of prostate symptoms.

Benign prostatic hyperplasia (BPH) is a major disease among ageing men and is the most common benign neoplasm, affecting almost 75% of men during the seventh decade of life. Valves are found to be incompetent or absent in the internal
15 spermatic veins of a large proportion of men of middle to later age found to have varicoceles. Varicoceles are found in 19 to 41 per cent of infertile American men. In men who were previously fertile and become infertile, the incidence is approximately 70 to 80 per cent. The relationship of varicoceles and benign prostatic hyperplasia has only recently been recognised and is now the subject of considerable research.
20 Although BPH is not ordinarily considered to be pre-malignant, it has also been postulated that exposure of the prostate to high free testosterone concentrations, now recognised as the most common cause of benign prostatic hyperplasia, may form part of the causal mechanism of prostatic carcinoma. Procedures have been studied for subjects with varicocele and diagnosed with early prostate cancer to undergo
25 venographic embolization of both spermatic veins with a view to neutralizing the causal mechanism. Conventional treatment of varicoceles includes surgical ligation of varicose vessels in the pampiniform venous plexus and sclerosis of the internal testicular vein to reduce the hydrostatic pressure imposed upon the testicular vessels, the latter generally producing a greater improvement in sperm quality. While no
30 estimate appears to have been made of the overall cost to society of varicoceles, BPH and related male infertility, these conditions are common and it will be readily understood that it is very considerable.

Cite prior art and critique - heart and vein valves - patents + literature

The first object of the present invention is to provide a prosthetic valve which is simple, efficient, robust and durable, which can be made in a range of sizes, which has minimal thrombogenic effect, and which is readily implantable as a replacement for the various forms of native valve in the human body. A second object of the present invention is to provide a prosthetic valve which may be made in larger forms for use as a heart valve. A third object of the present invention is to provide a prosthetic valve which may be made in smaller forms for use as a venous valve. A fourth object of the present invention is to provide a heart valve which mitigates many of the shortcomings of existing prosthetic heart valves. A fifth object of the present invention is to provide a heart valve which may be combined with a balloon-expandable stent, positioned in a collapsed state within a diseased valve of a beating heart using an endovascular or transapical approach, and subsequently expanded into place. A sixth object of the present invention is to provide a small vein valve which may be combined with a miniature stent and implanted percutaneously to reinstate the musculo-venous pump mechanism.

According to the present invention, a prosthetic valve for the heart or a vein comprises a more or less disk-like form created by spirally-winding a single element of a suitably elastic material into a number of partially overlapping and facially abutting layers. In their collapsed, abutting state, said partially overlapping layers provide a complete obstruction of flow in one direction but, when pressure is applied to them from the counter direction, they lift and elastically separate in a mode similar to that of the coils of a very light spring, providing a virtually unobstructed flow. Said overlapping element layers are optionally made flat, or curved, stepped or angled to create more or less conical or domed forms or inverted conical or domed forms. The upstream and downstream edges of said layers are optionally turned upwardly or downwardly, as appropriate, to better direct flow without turbulence. Guide rods are optionally provided to maintain said layers in alignment in their said collapsed state. Said valve is optionally mounted within a suitable stent and implanted in a partially collapsed state through the use of endovascular techniques, or is implanted directly using conventional open surgical techniques. Said valve is manufactured in a variety of ways from a wide variety of metal, non-metal and polymer materials. The materials from which said valve

is made is optionally solid, hollow, composite or internally reinforced.

The various aspects of the present invention will be more readily understood by reference to the following description of preferred embodiments given in relation to the accompanying drawings, in which:

5 Figure 1 is a transverse cross-sectional view of a section of blood vessel accommodating a valve made in accordance with one embodiment of the present invention;

 Figure 2 is a plan view of the valve of Figure 1;

 Figure 3 is a diagrammatic, transverse cross-sectional view of the valve
10 of Figure 1 during flow ;

 Figure 4 is a diagrammatic, transverse cross-sectional view of an alternative embodiment of the valve of Figure 1;

 Figures 5 to 10 are fragmentary, diagrammatic, cross-sectional views of alternative embodiments of the valve of Figure 1;

15 Figure 11 is a diagrammatic, transverse cross-sectional view of the valve of Figure 4 implanted as an aortic valve;

 Figure 12 is a diagrammatic transverse cross-sectional view of the vessel and valve of Figures 1 and 2;

 Figure 13 is a transverse cross-sectional view of a pre-form for the
20 making of a valving element of the present invention;

 Figure 14 is a side view of a valve fixed in collapsed form to its supporting ring;

 Figure 15 is a superior view of the valve and supporting ring of Figure
14;

25 Figure 16 is a fragmentary side view of an arrangement for the fixing of a valve to its supporting ring;

 Figure 17 is a diagrammatic plan view of modes of collapsing of a supporting ring.

30 No inference should be drawn from the fact that the various figures are drawn to differing scales. No inference should be drawn from the morphological differences in similar features depicted in different embodiments. In all longitudinal cross-sectional views of valves depicted in the figures, flow originates in the upstream zone beneath,

passing through a valve to the downstream zone above.

With reference to Figures 1 and 2, a prosthetic valve for a vein 3 comprises a single spirally-wound valving element 1 of a suitable thin and stiffly elastic material made in the form of a number of spirally arranged, partially overlapping layers. The final turn of said valving element terminates in capping piece 2 which acts as a central closure of said layers. In their collapsed, abutting state depicted, said partially overlapping layers provide a complete obstruction of flow in one direction but, when pressure is applied to them from the counter direction, they lift and elastically separate in a mode similar to that of the coils of a very light spring, providing a virtually unobstructed flow. In the preferred embodiment, the turns of said valving element overlap by between 20 per cent and 80 per cent of their width. Also in the preferred embodiment, said valving element is sealingly fixed at the end of its outer turn to annular supporting ring 4 which is, in turn, sealingly fixed to tubular stent 5. A circumferential band 6 of the material of said supporting ring extends through said stent and sealingly cooperates with the inner wall surface of said vein when said stent is properly installed in it. Said supporting ring is made from any suitable material, in the preferred embodiment, a soft, rubbery polymer, optionally reinforced internally with wire. In an alternative embodiment, said supporting ring is made from a suitable rigid material coated with a suitable polymer material. Said outer end zone of said valving element is suitably let in to the upper surface of said supporting ring to ensure that the superincumbent turn of said valving element sits sealingly upon it when said layers of said valving element are in their said collapsed state. The lower surface of the first turn of said valving element sealingly abuts the upper surface of said supporting ring when said valving element is in its collapsed state, the shaping of said valving element first turn and said supporting ring upper surface being complementary. Said stent takes a variety of the forms that are well known in the art, embodiments of smaller diameter being preferably of braided fine wire. The material from which said valving element is fabricated is optionally any suitable metal, metal alloy, metalloid, organic or inorganic material. Said valving element is optionally made solid and homogenous, solid and laminated in a single or two or more different materials, hollow, or solid with a tough, hard or elastic outer material encapsulating a softer, lighter or more flexible inner material. Said valving element is optionally reinforced internally with wires, strips of

metal or other elastic material of fabric of various kinds, said reinforcements being elastic or non-elastic. All parts of said valving element, said supporting ring and said stent are suitably treated to minimise thrombogenic tendencies. While said valving element is optionally made more or less flat in its collapsed form, in the preferred
5 embodiment, it is made domed (displaced in the direction of blood flow) to better accommodate vascular pressures applied to it. Said doming optionally ranges from approximately hemispherical to a height to width ratio of 1:12. In the preferred embodiment, said valve assembly is implanted in a vessel by first being collapsed into a compact form in the manner described elsewhere herein and inserted into a carrier tube
10 positioned on the end of a catheter. Said carrier tube is then introduced into the vessel and said carrier tube positioned as required using said catheter. Said valve assembly is then ejected from said carrier tube and permitted to expand into place or is expanded by balloon. In an alternative embodiment, the outer surface of circumferential band 6 is treated to encourage cell attachment to the vessel wall and said stent is made
15 bioabsorbable.

With reference to Figure 3, the valve of Figures 1 and 2 is depicted in its opened state with blood flow indicated by arrows 7. Pressure applied to said overlapping layers of said valving element from below has lifted and elastically separated said layers in a mode similar to that of the coils of a very light spring, resulting in a virtually
20 unobstructed flow. Supporting ring 4 is made with a more streamlined shape to prevent the pooling of blood below it and a streamlined fillet 8 is provided at its upper surface for the same purpose.

With reference to Figure 4, in order to provide a more streamlined flow of blood through said valve, said valving element is made with tapered and suitably deflected
25 upstream edges 12 and downstream edges 11. In this embodiment, said valving element is made thicker from a softly elastic, rubbery polymer material, reinforced internally with a thin, stiffly elastic reinforcement material 10 in the form of sheet, wires or the like. In the preferred embodiment, said reinforcement material is a carbon fibre composite, a thin, stiffly elastic polymer or metal, such as Nitinol, copper-beryllium alloy, chrome-
30 silicon spring steel, spring-tempered stainless steel, beta C titanium, Elgiloy, MP35N, Hastelloy or the like. Also in the preferred embodiment, the parent material of said valving element is a segmented polyurethane elastomer or segmented polyurethane

elastomer with a grafted polydimethylsiloxane film. While segmented polyurethane elastomers have proven suitable for prosthetic heart valve applications, surface calcification has proven a serious problem in long-term implants. Silicone modification of the polyurethane surface has been shown to successfully inhibit the calcification process. In alternative embodiments, other suitable elastomers are employed. Capping piece 13 is also shaped to maintain a streamlined flow around it and is optionally made solid, in hollow shell form or in shell form filled with foam or other less dense material. A streamlined fillet 15 is provided at the upper surface of the outer edge of supporting ring 4 which is made in streamlined form. In the preferred embodiment, supporting ring 4 is moulded into stent 5. In an alternative embodiment (not shown), said supporting ring and said stent are deleted and the lower turn of said valving element is fixed to a fixation band or sewing ring as incorporated into heart valves of conventional arrangement. In an alternative embodiment, the leading edges 12 of the turns of said valving element are deflected as depicted in the figure, but are made rounded instead of sharp.

With reference to Figure 5, a domed form of said valving element is created by making the transverse cross-sectional shape of said overlapping layers 16 in the form of upwardly angled steps. The first turn of said valving element is fixed to supporting ring 4 which is moulded to stent 5. Said valving element is closed by capping piece 17.

With reference to Figure 6, an inverted, domed form of said valving element is created by making the transverse cross-sectional shape of turns 18 in the form of downwardly angled steps, the upper and lower surfaces of said turns fully overlapping. The first turn of said valving element is fixed to supporting ring 4 which is moulded to stent 5. Said valving element is closed by capping piece 19.

With reference to Figure 7, a slightly domed form of said valving element is created by making the transverse cross-sectional shape of turns 20 flat and partially overlapping. Said first turn of said valving element is fixed to supporting ring 4 which is moulded to stent 5. Said valving element is closed by capping piece 21. Two or more inwardly projecting and upwardly angled guide wires 22 are optionally fixed to said supporting ring and, by abutting the inner edges of said turns of said valving element in their collapsed state, serve to accurately locate said turns.

With reference to Figure 8, a shallow, cylindrical form of said valving element is

created by making the transverse cross-sectional shape of turns 24 flat and fully overlapping. The first turn 23 of said valving element has a cranked cross-sectional shape to maintain said valving element turns clear of stent 5 and is fixed to supporting ring 4 which is moulded to said stent. Said valving element is closed by capping piece 5 25. Two or more downwardly projecting guide wires 26 are optionally fixed to the underside of said capping piece and, by abutting the inner edges of said turns of said valving element in their collapsed state, serve to accurately locate said turns.

With reference to Figure 9, a slightly inverted, domed form of said valving element is created by making the transverse cross-sectional shape of turns 28 slightly 10 downwardly curving, the surfaces of said turns partially overlapping. The first turn of said valving element is fixed to supporting ring 4 which is moulded to stent 5, a curved fillet 27 being provided at the upper, outer edge of said first turn to more efficiently direct flow. Said valving element is closed by capping piece 14.

With reference to Figure 10, a slightly domed form of said valving element is 15 created by making the transverse cross-sectional shape of turns 34 basically flat and partially overlapping. To provide more efficient flow, the upstream edges 33 and downstream edges 32 of said turns are deflected appropriately. Said first turn of said valving element is fixed to supporting ring 4 which is moulded to stent 5, a curved fillet 30 being provided at the upper, outer edge of said first turn to more efficiently direct 20 flow. The free end of said valving element is formed into a more or less circular capping piece 31 which completes said valve.

With reference to Figure 11, the valve of Figure 4 is supported from supporting ring 4, supplanting the aortic valve at the base of the ascending aorta. Said supporting ring is provided at its upper, outer circumference with upward and outwardly curving 25 fillet 38 which acts to maintain streamlined flow and prevent the pooling of blood in that zone. Said supporting ring has formed on its lower edge downward and outwardly curving collar 37 which passes beneath the aortic annulus, effectively enclosing said annulus. Said collar acts to maintain a streamlined flow and prevents the pooling of blood in that zone. Radially arranged sutures (not shown) are inserted through said 30 supporting ring to secure it permanently in place. In the preferred embodiment, suitably positioned pairs of apertures are provided in said supporting ring to accommodate said sutures, said pairs of apertures being joined at their inner ends by narrow, shallow

channels which accommodate suture loops passing between said pairs of apertures, maintaining said loops flush with the inner surface of said supporting ring. Internal plegeting of said sutures is unnecessary. In the preferred embodiment, the valving element 9 of said valve is made from the materials and reinforced in the manner

5 described in relation to Figure 4. Said supporting ring is selected for size and shape and, in the preferred embodiment, is made of a suitable polymer material which is optionally internally reinforced to maintain its shape and is treated to minimise thrombogenic tendencies. In this embodiment, capping piece 13 is made smaller than that depicted in Figure 4, is made in the manner described in relation to Figure 4 and is similarly shaped

10 to maintain a streamlined flow around it. In the preferred embodiment, in order to provide a more streamlined flow of blood through said valve, said valving element is made with tapered upstream edges 12 and downstream edges 11, said edges deflected towards the axis of the aorta. Said deflected edges are locally modified as required to generate a three-dimensional, helical blood flow pattern within said ascending aorta

15 similar in character to that of the natural flow pattern. To better encourage a streamlined flow around said capping piece, said downstream edges of said valving element closest to said capping piece are optionally more acutely deflected. The degree of overlap of the turns of said valving element is optionally adjusted to make the lines or zones of contact of said turns conform more or less to the shape of a conical or part-spherical body,

20 making said valve better able to sustain the forces applied by transvalvular pressure. The fixed end 57 of said valving element is fixed to said supporting ring at 58 in the manner described in relation to Figure 16. In an alternative embodiment (not shown), said valve is installed in the supra-annular position using a sewing ring of more or less conventional arrangement incorporated into said supporting ring. In an alternative

25 embodiment (not shown), said valve is installed in the ascending aorta.

With reference to Figure 12, in the preferred embodiment, valve 1, 2 is implanted in vessel 3 via longitudinal incision 42 (position and extent indicated in broken line). Said valve and its supporting ring 4 are inserted through said incision, positioned and secured by a plurality of circumferentially arranged sutures 40. Said sutures are passed

30 through pairs of suitable, radially arranged apertures 39 and are tied against restraining band 41 of suitable, non-elastic material. Shallow channels (not shown) are provided in the inner surface of said supporting ring joining each said pair of apertures, said channels

accommodating said sutures to maintain them more or less flush with the internal surface of said supporting ring. Said incision is closed in the normal way following implantation of said valve. In the preferred embodiment, said restraining band is made from a suitable biocompatible material, such as woven or braided Nitinol wire, or
5 woven, knitted or braided polymer filament or textile material such as Dacron or expanded PTFE. In an alternative embodiment, said restraining band takes the form of a proprietary product, such as Venocuff manufactured by Vaso Products, Inc, of Sommerville, NJ, USA, or the Vedensky spiral. Said restraining band acts to prevent dilatation of said vessel in the zone adjacent said valve.

10 With reference to Figure 13, a valving element of said valve is made by moulding a preform 53 in a suitable polymer material in the form of a stepped spiral comprising spirally arranged levels 43, 44, 45, 46. Attachment peg 47 is provided to fix said valving element to said supporting ring. To create said valving element, a sharp knife, saw or blade heated above the fusion temperature of the material is used to spirally
15 separate each level from the one above. It will be understood from an inspection of Figure 11 that this embodiment of said valving element may be created using the same method. Where said valving element is internally reinforced by means of wire or metal strip of a suitable elastic material, said internal reinforcement is kinked or otherwise provided with projections which act to locate said reinforcement in a mould, said mould
20 being filled with a suitable thermoplastic or thermosetting material to create a preform. Said preform is, in turn, made with projections which locate it within a second larger mould, said second mould then being filled with the same or another material to create a final form or, if appropriate, a second preform, which is completed in a third mould in a third phase of said moulding process. In an alternative embodiment, said valving
25 element is made from a suitable metal or metal alloy material and said levels are separated by means of chemical milling using a suitable wire as the cutting tool.

In an alternative embodiment (not shown), said valving element is fabricated by microwelding from separate pieces of a thin, suitable metal or metal alloy material joined to create said partially overlapping spiral form, said microwelding employing any
30 of the technology well known in the art. In the preferred embodiment, said components of said valving element are positionally supported during said fabrication process by miniature robotic

positioning means. Following its assembly by microwelding, said valving element is trimmed as required, preferably by laser or electrochemical means and electrochemically smoothed or electropolished before passivation, coating, or other treatment, as required. Said components of said valving element are optionally given three-dimensional shaping individually prior to said fabrication process or as a complete assembly upon completion of said fabrication process.

In an alternative embodiment (not shown), said valving element is formed by plasma spray into a suitable mould, a parting agent being progressively applied over each surface as forming proceeds. Following completion of its formation, said valving element is trimmed as required, preferably by laser or electrochemical means and electrochemically smoothed or electropolished before passivation, coating, or other treatment, as required. Said valving element is optionally given three-dimensional shaping upon completion of said forming process.

In an alternative embodiment (not shown), said valving element is formed by electrodeposition onto a suitable mould, an electrically conductive parting agent being progressively applied over each surface as forming proceeds. In this embodiment, said mould is preferably made to steadily rotate in relation to the anode. Following completion of its formation, said valving element is trimmed as required, preferably by laser or electrochemical means and electrochemically smoothed or electropolished before passivation, coating, or other treatment, as required. Said valving element is optionally given three-dimensional shaping upon completion of said forming process. In an optional alternative of this embodiment, said valving element is formed by electroless deposition.

In an alternative embodiment (not shown), said valving element is formed by 3D inkjet printing and sintering, a suitable heat-tolerant parting medium being deposited between each layer. In this embodiment, the formed material is preferably deposited onto a steadily rotating mould. In the preferred embodiment, pressureless sintering in a controlled atmosphere furnace is employed, temperatures and sintering times being adjusted to provide the desired degree of densification. Materials optionally used to manufacture said valving element include glasses, metals, metal alloys, other non-metals and polymers. Where appropriate, post-forming treatments of the types previously described are applied. Said parting media include graphite, alumina, zirconia and

magnesia, which may be applied as a coating on a sacrificial film. To optionally provide increased density, following the initial sintering process, said valving element is reheated in a controlled atmosphere and then subjected to high pressure in a suitable die.

In other alternative embodiments (not shown), said valving element is formed
5 by electron beam melting of metal powder stock, by electron beam free-form fabrication from wire feedstock, by fused deposition modelling from liquid thermoplastic material, or by laser engineered net shaping from metal powder. In the preferred embodiment, as previously described, forming takes place in a steadily rotating die, a suitable, heat-tolerant parting medium being deposited between each layer. Where appropriate, post-
10 forming treatments of the types previously described are applied. To optionally provide increased density, following the initial sintering process, said valving element is reheated in a controlled atmosphere and then subjected to high pressure in a suitable die. Where said metal material is Nitinol created by the sintering of Ni and Ti powders and subsequently hot compressed in a suitable die in controlled atmosphere and at a suitable
15 temperature, the characteristic shape-memory and superelasticity effects of Nitinol are achieved.

In another alternative embodiment (not shown), said valving element is formed by extrusion of a continuous thin strip of a suitable polymer material from a shaped die onto a steadily rotating mould, a suitable parting medium being applied to each layer. In
20 an optional alternative of this embodiment, a pultrusion process is employed using a suitable filamentary reinforcement material in a suitable thermosetting or thermoplastic polymer.

In another alternative embodiment (not shown), said valving element is formed in layers by spray coating or plasma polymerization. PTFE is spray coated and cured at
25 temperatures above 300 degrees C. PTFE, polyurethane, parylene or the like are deposited by plasma polymerization.

In other alternative embodiments (not shown), said valving element is formed in layers by plasma spraying, physical vapour deposition, ion plating, plasma-based plating or sputter deposition from suitable materials, other techniques previously described
30 being optionally applied.

In another alternative embodiment (not shown), said valving element is formed by laser heating of a progressively advancing stretching zone of a thin, continuous strip

of glass or polymer material, said heating being above the glass transition temperature of the material to permit said strip to be locally stretched as said stretching zone passes along it and be spirally wound over a continuously rotating suitable mould or former. Said strip is optionally made with a tapering cross-sectional form such that, when said strip is stretched into said spiral arrangement, it assumes a parallel cross-sectional form or other form, if desired. If necessary, a suitable parting medium is continuously applied to the formed strip to prevent adhesion of a superincumbent layer.

In another alternative embodiment (not shown), said valving element is formed by laser heating of a progressively advancing zone of an array of glass or polymer filaments above the glass transition temperature of the material, said array first being deformed and spirally wound over a continuously rotating suitable mould or former before being fused together to form a strip. If necessary, a suitable parting medium is continuously applied to the formed strip to prevent adhesion of a superincumbent layer.

In another alternative embodiment (not shown), said valving element is formed by laser heating of a progressively advancing zone of an array of abutting, parallel glass or metal filaments coated with a thermoplastic polymer, said array first being deformed and spirally wound over a continuously rotating suitable mould or former before said polymer is heated above its glass transition temperature to fuse said coated filaments together to form a strip. If necessary, a suitable parting medium is continuously applied to the formed strip to prevent adhesion of a superincumbent layer.

In another alternative embodiment (not shown), said valving element is formed by laser heating of a progressively advancing zone of an array of abutting, parallel glass or metal filaments coated with a thermosetting polymer, said array first being deformed and spirally wound over a continuously rotating suitable mould or former before said polymer is heated to set said polymer and fuse said coated filaments together to form a strip. If necessary, a suitable parting medium is continuously applied to the formed strip to prevent adhesion of a superincumbent layer.

In another alternative embodiment (not shown), said valving element is formed by UV or other irradiation of a progressively advancing zone of an array of abutting, parallel glass or metal filaments coated with a radiation-curing polymer, said array first being deformed and spirally wound over a continuously rotating suitable mould or former before said polymer is irradiated to set said polymer and fuse said coated

filaments together to form a strip. If necessary, a suitable parting medium is continuously applied to the formed strip to prevent adhesion of a superincumbent layer.

Coatings of said valving element optionally include but are not limited to polytetrafluoroethylene; polyurethane (PU); segmented polyurethane; 5 polymethylsiloxane; non-porous silicone polymer coating on PTFE; self-assembling silane monolayer; silyl-heparin coating using PEG as a cross-linking agent; pyrolytic carbon; amorphous diamond-like carbon (DLC); turbostratic carbon; silicon; silicon dioxide; silicon nitride; silicon carbide; synthesised mussel adhesive polypeptide; heparin attached via amine functional groups; gelatin-glutaraldehyde cross-linked on 10 silicone rubber; type 1 collagen attached via ion beam surface modification; polypeptide multilayer or polymer, enzyme or nanoparticle film generated electrostatically layer-by-layer; adhesive polypeptide and anti-CD34 antibody; heparin-collagen multilayer with anti-CD34 antibody; glycosaminoglycans and antithrombin III; monomeric conjugate containing benzamidine modified with PEG spacer; photocured gelatin or microporous 15 thin segmented polyurethane seeded with endothelial progenitor cells; plasma polymerized *n*-butyl methacrylate; dextran-40 in photocured gelatin or gelatin/alginate hydrogel; forskolin or forskolin agarose; heparin stabilized ionically bonded to polyurethane or covalently bonded to PTFE; Rapamycin-coated PTFE; heparin/collagen multilayer; heparin covalently bonded by end-point attachment to polyethylene; waxes, 20 including candelilla, spermaceti, bees, carnauba, carbowax and paraffin; bacterial cellulose in hydroxyethylcellulose or other matrix; alkanethiol self-assembling monolayer with -OH OR -COOH surface groups optionally with plasma albumen absorbed onto the surface; self-assembling monolayers of bromoethylphosphate-, phosphorylcholine-, phosphorylethanolamine-, hydroxyl-terminated polymers or self-assembling monolayers, poly(carboxybetaine methacrylate) polymer, or polystyrene 25 coated with a copolymer of L-histidine, a zwitterion, *n*-butyl methacrylate and hydrophobic moiety; polymer brushes containing sulfated carbohydrate repeat units resembling surface-tethered heparin; polysaccharide-based glycocalyx-mimicking polymer coating; free ϵ -amino surface groups incorporated using PEG-lysine conjugates; 30 polyurethane coated with a lysine-derivatized acrylamide polymer; nanocomposite fibrinolytic coatings comprising proteolytic enzymes tethered to the surfaces of carbon nanotubes and dispersed in poly (methyl methacrylate), enzymes such as serine protease,

subtilisin Carlsberg and trypsin, the enzymes being loaded onto the carbon nanotubes by physisorption and a fibrinolytic enzyme being optionally incorporated into the coatings; a low-leaching, NO-generating polyelectrolyte multilayer thin film comprising sodium alginate and organoselenium-modified polyethyleneimine prepared by layer-by-layer assembly on a silicone rubber or polyurethane substrate; polyelectrolyte multilayer coatings of chitosan and dextran sulfate on poly (tetramethylene adipate-co-terephthalate, L-arginine being optionally incorporated; polyurethane coatings incorporating hyaluronic acid as a chain extender during polyurethane synthesis; poly (ester urethane) dip-coated with an amphiphilic conjugate of stearyl poly (ethylene oxide) with 4,4'-methylene diphenyl diisocyanate, a film-building additive in the form of a polytetramethylene glycol-based polyurethane elastomer being incorporated; polymer coatings of paracyclophane derivatives co-deposited in controlled ratios by chemical vapour deposition as functionalized coatings polymerized into poly (*p*-xylenes) during the deposition process; heparin immobilized on silicone via a heterobifunctional PEG spacer. Treatments of said valving element optionally include but are not limited to doping (fluorine doped DLC) or the provision of functionalized endgroups (PU) for attachment of a variety of compounds. The purpose of said coatings and said treatments is to reduce thrombogenicity and encourage endothelialisation. Said coatings and said treatments are optionally applied to said supporting ring and to stents employed with said valve. Any feasible combination of one or more of said coatings and one or more of said treatments is optionally employed.

With reference to Figures 14, 15 and 17, said valve is collapsed into compact form to facilitate endovascular implantation. With specific reference to Figures 14 and 15, supporting ring 4 is restrained and said valving element is rotationally tensioned from capping piece 2 such that the coils of said valving element assume the form of compact, nested, conical spiral turns 48, 49, 50. With additional reference to Figure 17, supporting ring 4 is collapsed inwardly commencing at a point diametrically opposite the point of attachment of said valving element to said supporting ring. Partial collapse is depicted at 55, further collapse into a partially doubled, circular form is depicted 56 and complete collapse into a compact, circular form is depicted at 54. It will be appreciated that, given a suitable degree of elasticity of said valving element and said supporting ring, said valve may readily be collapsed into less than half its normal diameter, with

further collapsed into a more compact form possible. In this embodiment, said supporting ring is fixed in correct orientation within the distal end of a suitable expandable stent and collapsed into compact form. Said stent and said valve are then drawn into a thin metal sleeve supported on the distal end of a catheter with a deflated
5 balloon within said stent. Said metal sleeve is entered into a vessel and accurately located at the implantation site. Said stent and valve are ejected from said metal sleeve and said balloon inflated to restore said stent to its proper shape, said supporting ring and said valving element extending to assume their proper shapes. Said balloon is deflated and drawn into said metal sleeve and said catheter withdrawn from said vessel.

10 With reference to Figure 16, in the preferred embodiment, valving element 1 is provided at its fixed end with an attachment peg 47 which is permanently accommodated within a complementary bore in boss 52 formed on supporting ring 4. Tapered rebate 51 of suitable depth is provided in the upper surface of said supporting ring such that the second turn of said valving element lies neatly on top of the first turn
15 of said supporting ring without clearance.

Said valve embodiment offers multiple advantages for employment as a prosthetic heart valve. At commencement of valve opening and at final closing, because seating is effectively distributed over more or less the full lengths of said valving element and said supporting ring, there is no generation of the release or choke jet
20 common with some mechanical prosthetic valves. As a result, cavitation and its deleterious consequences are avoided. In opening, said valve creates a spirally arranged and relatively narrow aperture extending along more or less the full lengths of said valving element and said supporting ring, rather than the large single opening of a mechanical prosthetic valve. Importantly, said aperture is distributed over the full area
25 of said valve. During closing of said valve, as the average width of said aperture is relatively small, interruption of flow occurs more rapidly than, for example, the valving elements of a mechanical prosthetic valve. The result is a minimising of regurgitation volume. For the same reason and because said valving element is made from a resilient material, at closing there is no occluder impact common with mechanical prosthetic
30 valves of conventional arrangement. Similarly, elastic compliance permits said valving element to readily accommodate the sharp increase in loading resulting from the rise in transvalvular pressure. Opening of said valve involves only a small torsional distortion

distributed more or less equally throughout the whole length of said valving element, said distortion applying only minimal stress. Said valving element incorporates no hinges or other mechanical components and impact and frictional wear are negligible. The result is a very low risk of fatigue or simple mechanical failure. The spiral arrangement of said valving element and the distributed nature of said spirally-arranged aperture when said valve is open provide a greater effective aperture than those of many configurations of mechanical prosthetic valve. Said valving element is readily able to be modified to provide a streamlined flow through said valve and in the downstream zone, with minimal flow separation and turbulence. Unlike many prosthetic valves, all surface of said valve and adjacent anatomical structures are swept by blood at each opening and the arrangement of said valve makes it possible to prevent stagnation of blood in the zone adjacent said valve. Said valve thus reduces thrombogenic effects. Low seating forces in said valving element minimises erythrocyte damage, reducing the possibility of haemolytic anaemia. When incorporated, metal components of said valve are completely encapsulated and exposed polymer surfaces are treated to reduce thromogenetic effects.

Said valve is able to be employed in any situation in which valvular incompetence requires rectification.

Said valve is elastically compliant, radial pressure applied to said valving element being accommodated by sliding displacement of its said turns one to another without their being unseated.

Depending upon the elastic characteristics of the particular material, the thickness of said turns of said valving element is optionally made between 0.01 millimetre and 4 millimetres.

In an alternative embodiment (not shown), said valving element is made in composite or laminated form with one or more layers of a soft flexible material laminated with one or more layers of a stiffly flexible material. In this embodiment, the thickness and width of said layers are varied to provide desired physical characteristics.

In an alternative embodiment (not shown), said valving element is made from a thin, superelastic metal, such as nitinol, the superelastic characteristics of said material being exploited to permit said valve to be collapsed into compact form to facilitate implantation.

In an alternative embodiment (not shown), the local width and thickness of said turns of said valving element are adjusted to ensure a consistent pressure-generated displacement response throughout all parts of said valving element.

5 In an alternative embodiment (not shown) said valving element is made with a greater or lesser number of turns to suit the needs of a particular application. The number of turns optionally varies between 1 and 10.

In an alternative embodiment (not shown), the valving element of a said valve is optionally collapsed into compact form to facilitate implantation of said valve by winding said valving element around and along a thin cylinder.

10 In an alternative embodiment (not shown), in order to manipulate flow characteristics through a said valve and in zones adjacent it, the complex cross-sectional shaping of a said valving element is optionally locally varied.

In alternative embodiments (not shown), all valving elements are optionally made with deflected leading edges and trailing edges, said edges being optionally made sharp or rounded.

In an alternative embodiment (not shown), the first (lowest) said turn of a said valving element and/or said supporting ring are optionally made thicker and narrower and shaped to facilitate flow past them, thereby preventing the pooling of blood beneath them.

20 In an alternative embodiment (not shown), the degree of overlap of said turns of said valving element is varied at different parts of said valving element, a consistent seating force being achieved throughout said valving element by increasing overlap in turns of larger diameter and decreasing overlap in turns of smaller diameter, reduced overlap being acceptable in turns of smaller diameter owing to their better positional stability.

In an alternative embodiment (not shown), deflected leading and trailing edges of successive said turns of said valving element are made to nest closely.

In an alternative embodiment (not shown) and particularly in larger embodiments of said valve, the fixed end of the first (lowest) said turn of said valving element is
30 optionally supported from said supporting ring by one or more thin, narrow elastic elements embedded securely in said valving element and said supporting ring and accommodated for a suitable length in complementary channels formed in the upper

surface of said supporting ring. With opening of said valve, said elastic elements are free to rise upwardly from said channels and their free length is such as to permit the fixed end of said valving ring to rise clear of said supporting ring, thereby ensuring that the attachment zone of said valving element and said supporting ring is continuously swept by blood and that stagnation does not occur. In the closed position of said valve, the end of said valving element just contacts the slightly angled end surface of a rebate (depicted as 51 in Figure 16) provided in said supporting ring. In the preferred embodiment, said elastic elements take the form of highly polished, elastic, round metal wire.

10 In an alternative embodiment (not shown), said valving element is made with its surfaces covered in a biological material, such as fibrous pericardium.

In an alternative embodiment (not shown) and particularly in larger embodiments of said valve, a capping piece (depicted as 13 in Figure 4) is made hollow from a suitable softly flexible material and is able to be collapsed for endovascular implantation, said capping piece being inflated after implantation by a slow chemical reaction generating a
15 settable polymer foam.

In an alternative embodiment (not shown), a narrow, slightly raised, annular sealing surface is optionally provided along the surfaces of said valving element. In this embodiment, said raised sealing surface is optionally situated medially on both surfaces of said turns or at the outer edge of the lower surfaces of said turns or the inner edge of the upper surfaces of said turns.
20

In an alternative embodiment (not shown), said valving element and said supporting ring are formed in a single piece. In this embodiment, said valving element and said supporting ring are formed using a suitable 3D forming process and subsequently heated or subjected to another densification process.
25

In alternative embodiments (not shown), and feasible combination of any one of more of the described features with any other one or more features is employed.

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CLAIMS

1. A prosthesis to replace a venous or cardiac valve comprising a valving element in the form of a plurality of spirally-arranged, partially overlapping and facially abutting layers, said valving element being made in a single piece from a thin, elastic material, the end of its outer turn being fixed to an annular supporting ring and the end of its final turn terminating in a capping piece which acts as a central closure of said layers; in their collapsed and abutting state, said partially overlapping layers acting to provide a complete obstruction to flow in one direction but, when pressure is applied to them from the counter direction, lifting and elastically separating in a mode similar to that of the coils of a very light spring; opening of said valve involving only a small torsional distortion distributed more or less equally throughout the whole length of said valving element, said valving element incorporating no hinges or other mechanical components which might be subject to impact damage or frictional wear, the distributed nature of said spirally-arranged aperture of the open said valve providing a large effective aperture.
2. The prosthetic valve of Claim 1 in which the turns of said valving element overlap by between 20 per cent and 80 per cent of their width.
3. The prosthetic valve of Claim 1 in which said spiral arrangement is cylindrical or is tapered to varying degrees.
4. The prosthetic valve of Claim 1 in which said annular supporting ring is made with a spirally-tapered step to ensure that the superincumbent first turn of said valving element sits sealingly upon it when said layers of said valving element are in their said collapsed state.
5. The prosthetic valve of Claim 1 in which the lower surface of said first turn of said valving element sealingly abuts the upper surface of said annular supporting ring when said valving element is in its said collapsed state.
6. The prosthetic valve of Claim 1 in which said annular supporting ring is fixed to and supported in a tubular stent, a circumferential band of the material of said supporting ring extending through said stent and sealingly cooperating with the inner wall surface of a vessel in which said stent is implanted.
7. The prosthetic valve of Claim 1 in which the structure and material of said stent

take any common form.

8. The prosthetic valve of Claim 1 in which said stent is made from braided fine wire.
9. The prosthetic valve of Claim 1 in which said valving element is made from any
5 suitable metal, metal alloy, metalloid, organic material or inorganic material.
10. The prosthetic valve of Claim 1 in which said valving element is made solid and homogenous, solid and laminated in a single or two or more different materials, hollow, or solid with a tough, hard or elastic outer material encapsulating a softer, lighter or more flexible inner material.
- 10 11. The prosthetic valve of Claim 1 in which said valving element is reinforced internally with wires, strips of metal or other elastic material or fabric of various kinds, said reinforcements being elastic or non-elastic.
12. The prosthetic valve of Claim 1 in which all parts of said valving element, said supporting ring and said stent are suitably treated to minimise thrombogenic
15 tendencies.
13. The prosthetic valve of Claim 1 in which said annular supporting ring is made from a soft, rubbery polymer material.
14. The prosthetic valve of Claim 1 in which said annular supporting ring is reinforced internally with wire.
- 20 15. The prosthetic valve of Claim 1 in which said annular supporting ring is made from a suitable rigid material coated with a suitable polymer material.
16. The prosthetic valve of Claim 1 in which said valving element is made in a range of transverse cross-sectional shapes in its collapsed form, said shapes ranging from more or less flat to domed; said doming being a symmetrically curved
25 displacement in the direction of blood flow and provided to render said valve better able to accommodate pressures applied to it.
17. The prosthetic valve of Claim 16 in which said doming of said valving element ranges from approximately hemispherical to a height to width ratio of 1:12.
18. The prosthetic valve of Claim 1 which is implanted in a vessel by first being
30 collapsed into a compact form and inserted into a carrier tube positioned on the end of a catheter; said carrier tube then being introduced into said vessel and positioned as required using said catheter; said valve then being ejected from

said carrier tube and permitted to elastically expand into place or being expanded into place by means of a balloon.

19. The prosthetic valve of Claim 1 in which the outer surface of said circumferential supporting ring is treated to encourage cell attachment to the vessel wall and said stent is made bioabsorbable.
20. The prosthetic valve of Claim 1 in which said annular supporting ring is made with its lower surfaces streamlined to prevent the pooling of blood below said ring.
21. The prosthetic valve of Claim 1 in which said annular supporting ring is made with a streamlined fillet at its upper surface to prevent the pooling of blood above said ring.
22. The prosthetic valve of Claim 1 in which, in order to provide a more streamlined flow of blood through said valve, said turns of said valving element are made tapered - arranged in the form of a shallow cone - and with the leading (upstream) and trailing (downstream edges) of each said turn suitably deflected.
23. The prosthetic valve of Claim 22 in which said downstream edges taper to a knife edge and said upstream edges are rounded or tapered to a knife edge.
24. The prosthetic valve of Claim 22 in which said valving element is made thicker from a softly elastic, rubbery polymer material and reinforced internally with a thin, stiffly elastic reinforcement material.
25. The prosthetic valve of Claim 24 in which said polymer material is a segmented polyurethane elastomer or segmented polyurethane elastomer coated with a grafted polydimethylsiloxane film.
26. The prosthetic valve of Claim 24 in which said polymer material is any of those well known in the art for the making of biomedical devices.
27. The prosthetic valve of Claim 24 in which said internal reinforcement takes the form of sheet, wires or the like of a carbon fibre composite, polymer or metal, such as Nitinol, copper-beryllium alloy, chrome-silicon spring steel, spring-tempered stainless steel, beta C titanium, Elgiloy, MP35N, Hastelloy or the like.
28. The prosthetic valve of Claim 1 in which said capping piece is shaped to maintain a streamlined flow around it and is optionally made solid, in hollow shell form or in shell form filled with foam or other less dense material.

29. The prosthetic valve of Claim 1 in which said annular supporting ring and said stent are deleted and the end of the lower turn of said valving element is fixed to a fixation band or sewing ring of the type incorporated into prosthetic heart valves of conventional arrangement.
- 5 30. The prosthetic valve of Claim 1 in which said valving element is made in a domed form created by making the transverse cross-sectional shape of said overlapping turns in the form of upwardly angled steps, the upper and lower surfaces of said turns being more or less fully overlapping.
- 10 31. The prosthetic valve of Claim 1 in which said valving element is made in an inverted, domed form created by making the transverse cross-sectional shape of said overlapping turns in the form of downwardly angled steps, the upper and lower surfaces of said turns being more or less fully overlapping.
- 15 32. The prosthetic valve of Claim 1 in which said valving element is made in a flat or slightly domed form created by making the transverse cross-sectional shape of said turns flat and partially overlapping; two or more wires fixed to said annular supporting ring projecting inwardly and angled upwardly, by abutting the inner edges of said turns of said valving element in their collapsed state, said wires serve to accurately locate said turns.
- 20 33. The prosthetic valve of Claim 1 in which said valving element is made in a shallow, cylindrical form created by making the transverse cross-sectional shape of said turns flat and fully overlapping, the first turn of said valving element having a cranked cross-sectional shape to maintain said valving element turns clear of said stent, two or more downwardly projecting guide wires fixed to the underside of said capping piece, by abutting the inner edges of said turns of said
- 25 valving element in their collapsed state, said wires serve to accurately locate said turns.
- 30 34. The prosthetic valve of Claim 1 in which said valving element is made in a slightly inverted, domed form created by making the transverse cross-sectional shape of said turns slightly downwardly curving, the surfaces of said turns partially overlapping.
35. The prosthetic valve of Claim 1 in which said valving element is made in a slightly domed form created by making the transverse cross-sectional shape of

said turns basically flat and partially overlapping, to provide more efficient flow, the upstream edges and downstream edges of said turns being deflected appropriately.

- 5 36. The prosthetic valve of Claim 1 in which said valving element is supported from an annular supporting ring supplanting the aortic valve at the base of the ascending aorta, said supporting ring being provided at its upper, outer circumference with an upwardly and outwardly curving fillet which acts to maintain streamlined flow and prevent the pooling of blood in that zone; said supporting ring having formed on its lower edge a downward and outwardly
- 10 curving collar which passes beneath and effectively encloses the aortic annulus, said collar acting to maintain a streamlined flow and prevent the pooling of blood in that zone; radially arranged sutures being inserted through said supporting ring to secure it permanently in place, suitably positioned pairs of apertures being provided in said supporting ring to accommodate said sutures,
- 15 said pairs of apertures being joined at their inner ends by narrow, shallow channels which accommodate suture loops passing between said pairs of apertures and maintain said loops flush with the inner surface of said supporting ring.
- 20 37. The prosthetic valve of Claim 36 in which, in order to provide a more streamlined flow of blood through said valve, said edges of said valving element are deflected towards the axis of the aorta and said deflected edges are locally modified to generate a three-dimensional, helical blood flow pattern within said ascending aorta similar in character to that of the natural flow pattern.
- 25 38. The prosthetic valve of Claim 36 in which, in order to better encourage a streamlined flow around said capping piece, said downstream edges of said valving element closest to said capping piece are more acutely deflected.
- 30 39. The prosthetic valve of Claim 36 in which, in order to better sustain forces applied by transvalvular pressure, the degree of overlap of said turns of said valving element is adjusted to make the lines or zones of contact of said turns conform more or less to the shape of a conical or part-spherical body.
40. The prosthetic valve of Claim 36 which is installed in the supra-annular position using a sewing ring of more or less conventional arrangement incorporated into

said annular supporting ring.

41. The prosthetic valve of Claim 36 which is installed in the ascending aorta.

42. The prosthetic valve of Claim 1 which is implanted in a vessel via a longitudinal incision, said valve and its said annular supporting ring being inserted through
5 said incision, positioned and secured by a plurality of circumferentially arranged sutures; said sutures being passed through pairs of suitable, radially arranged apertures and tied against an external restraining band of suitable, non-elastic material, shallow channels being provided in the inner surface of said supporting ring joining each said pair of apertures, said channels accommodating said
10 sutures and maintaining them more or less flush with the internal surface of said supporting ring.

43. The prosthetic valve of Claim 42 in which said restraining band is made from a suitable biocompatible material, such as woven or braided Nitinol wire, or
15 woven, knitted or braided polymer filament or textile material such as Dacron or expanded PTFE.

44. The prosthetic valve of Claim 42 in which said restraining band takes the form of a proprietary product of the type normally employed to prevent dilatation of a vessel in the zone adjacent a valve.

45. The prosthetic valve of Claim 1 in which said valving element is made by
20 moulding a preform in a suitable polymer material in the form of a stepped spiral comprising spirally arranged levels, an attachment peg being provided to fix said valving element to said supporting ring; said valving element being created by using a sharp knife, saw or blade heated above the fusion temperature of the material to spirally separate each said level from the one above.

46. The prosthetic valve of Claim 45 in which, where said valving element is
25 internally reinforced by means of wire or metal strip of a suitable elastic material, before moulding of said preform, said internal reinforcement is kinked or otherwise provided with projections which act to locate said reinforcement in a mould, said mould being filled with a suitable thermoplastic or thermosetting
30 material to create said preform; said preform, in turn, being made with projections which locate it within a second larger mould, said second mould then being filled with the same or another material to create a final form or, if

appropriate, a second preform, which is completed in a similar manner in a third mould in a third phase of said moulding process.

47. The prosthetic valve of Claim 45 in which said valving element is made from a suitable metal or metal alloy material and said levels are separated by means of chemical milling using a suitable wire as the cutting tool.

48. The prosthetic valve of Claim 1 in which said valving element is fabricated by microwelding from separate pieces of a thin, suitable metal or metal alloy material joined to create said partially overlapping spiral form, said components of said valving element being positionally supported during said fabrication process by miniature robotic positioning means.

49. The prosthetic valve of Claim 48 in which, following its assembly by microwelding, said valving element is trimmed as required by laser or electrochemical means and electrochemically smoothed or electropolished before passivation, coating, or other treatment, as required.

50. The prosthetic valve of Claim 48 in which said component pieces of said valving element are given three-dimensional shaping individually prior to said fabrication process or as a complete assembly upon completion of said fabrication process.

51. The prosthetic valve of Claim 1 in which said valving element is formed by plasma spraying of material into a suitable mould, a parting agent being progressively applied over each surface as forming proceeds.

52. The prosthetic valve of Claim 51 in which, following completion of its formation, said valving element is trimmed as required by laser or electrochemical means and electrochemically smoothed or electropolished before passivation, coating, or other treatment, as required.

53. The prosthetic valve of Claim 51 in which said valving element is given three-dimensional shaping upon completion of said forming process.

54. The prosthetic valve of Claim 1 in which said valving element is formed by electroless or electrodeposition of material onto a suitable mould, an electrically conductive parting agent being progressively applied over each surface as forming proceeds. In this embodiment, said mould being made to steadily rotate in relation to the anode.

55. The prosthetic valve of Claim 54 in which, following completion of its formation, said valving element is trimmed as required by laser or electrochemical means and electrochemically smoothed or electropolished before passivation, coating, or other treatment, as required.
- 5 56. The prosthetic valve of Claim 54 in which said valving element is given three-dimensional shaping upon completion of said forming process.
57. The prosthetic valve of Claim 1 in which said valving element is formed by inkjet printing and sintering, a suitable heat-tolerant parting medium being deposited between each layer as it is deposited onto a steadily rotating mould; pressureless sintering in a controlled atmosphere furnace being employed with temperatures and sintering times being adjusted to provide the desired degree of densification.
- 10 58. The prosthetic valve of Claim 57 in which materials employed to form said valving element include glasses, metals, metal alloys, other non-metals and polymers, said parting media including graphite, alumina, zirconia and magnesia applied as a coating on a sacrificial film; to provide increased density following the initial sintering process, said valving element being reheated in a controlled atmosphere and then subjected to high pressure in a suitable die.
- 15 59. The prosthetic valve of Claim 1 in which said valving element is formed by electron beam melting of metal powder stock, by electron beam free-form fabrication from wire feedstock, by fused deposition modelling from liquid thermoplastic material, or by laser engineered net shaping from metal powder, said forming taking place in a steadily rotating die and a suitable, heat-tolerant parting medium being deposited between each layer; to provide increased density following the initial sintering process, said valving element is reheated in a controlled atmosphere and then subjected to high pressure in a suitable die.
- 20 60. The prosthetic valve of Claim 59 in which, where said metal material is Nitinol created by the sintering of Ni and Ti powders and subsequently hot compressed in a suitable die in controlled atmosphere and at a suitable temperature, the characteristic shape-memory and superelasticity effects of Nitinol are achieved.
- 25 61. The prosthetic valve of Claim 1 in which said valving element is formed by extrusion of a continuous thin strip of a suitable polymer material from a shaped
- 30

die onto a steadily rotating mould, a suitable parting medium being applied to each layer.

5 62. The prosthetic valve of Claim 1 in which said valving element is formed by a pultrusion process using a suitable filamentary reinforcement material in a suitable thermosetting or thermoplastic polymer, said material being extruded from a shaped die onto a steadily rotating mould, a suitable parting medium being applied to each layer.

10 63. The prosthetic valve of Claim 1 in which said valving element is formed in layers by spray coating or plasma polymerization, PTFE being spray coated and cured at temperatures above 300 degrees C, PTFE, polyurethane, parylene or the like being deposited by plasma polymerization onto a steadily rotating mould, a suitable parting medium being applied to each layer.

15 64. The prosthetic valve of Claim 1 in which said valving element is formed in layers by plasma spraying, physical vapour deposition, ion plating, plasma-based plating or sputter deposition from suitable materials, said materials being deposited onto a steadily rotating mould, a suitable parting medium being applied to each layer.

20 65. The prosthetic valve of Claim 1 in which said valving element is formed by laser heating of a progressively advancing stretching zone of a thin, continuous strip of glass or polymer material, said heating being above the glass transition temperature of the material to permit said strip to be locally stretched as said stretching zone passes along it and be spirally wound over a continuously rotating suitable mould or former; said strip optionally being made with a tapering cross-sectional form such that, when said strip is stretched into said spiral arrangement, it assumes a parallel or other cross-sectional form; a suitable parting medium being continuously applied to the formed strip to prevent adhesion of a superincumbent layer.

25 30 66. The prosthetic valve of Claim 1 in which said valving element is formed by laser heating of a progressively advancing zone of an array of glass or polymer filaments above the glass transition temperature of the material, said array first being deformed and spirally wound over a continuously rotating suitable mould or former before being fused together to form a strip; if necessary, a suitable

parting medium being continuously applied to the formed strip to prevent adhesion of a superincumbent layer.

- 5 67. The prosthetic valve of Claim 1 in which said valving element is formed by laser heating of a progressively advancing zone of an array of abutting, parallel glass or metal filaments coated with a thermoplastic or thermosetting polymer, said array first being deformed and spirally wound over a continuously rotating suitable mould or former before said polymer is heated above its glass transition temperature, thereby fusing said coated filaments together to form a strip; if necessary, a suitable parting medium being continuously applied to the formed strip to prevent adhesion of a superincumbent layer.
- 10 68. The prosthetic valve of Claim 1 in which said valving element is formed by UV or other irradiation of a progressively advancing zone of an array of abutting, parallel glass or metal filaments coated with a radiation-curing polymer, said array first being deformed and spirally wound over a continuously rotating suitable mould or former before said polymer is irradiated to set said polymer and fuse said coated filaments together to form a strip; if necessary, a suitable parting medium being continuously applied to the formed strip to prevent adhesion of a superincumbent layer.
- 15 69. The prosthetic valve of Claim 1 in which, to encourage endothelialisation or to minimise thrombogenetic effects, said valving element is coated with any of or any combination of polytetrafluoroethylene; polyurethane (PU); segmented polyurethane; polymethylsiloxane; non-porous silicone polymer coating on PTFE; self-assembling silane monolayer; silyl-heparin coating using PEG as a cross-linking agent; pyrolytic carbon; amorphous diamond-like carbon (DLC); turbostratic carbon; silicon; silicon dioxide; silicon nitride; silicon carbide; synthesised mussel adhesive polypeptide; heparin attached via amine functional groups; gelatin-glutaraldehyde cross-linked on silicone rubber; type 1 collagen attached via ion beam surface modification; polypeptide multilayer or polymer, enzyme or nanoparticle film generated electrostatically layer-by-layer; adhesive polypeptide and anti-CD34 antibody; heparin-collagen multilayer with anti-CD34 antibody; glycosaminoglycans and antithrombin III; monomeric conjugate containing benzamidine modified with PEG spacer; photocured gelatin or
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microporous thin segmented polyurethane seeded with endothelial progenitor cells; plasma polymerized *n*-butyl methacrylate; dextran-40 in photocured gelatin or gelatin/alginate hydrogel; forskolin or forskolin agarose; heparin stabilized ionically bonded to polyurethane or covalently bonded to PTFE; Rapamycin-coated PTFE; heparin/collagen multilayer; heparin covalently bonded by end-point attachment to polyethylene; waxes, including candelilla, spermaceti, bees, carnauba, carbowax and paraffin; bacterial cellulose in hydroxyethylcellulose or other matrix; alkanethiol self-assembling monolayer with -OH OR -COOH surface groups optionally with plasma albumen absorbed onto the surface; self-assembling monolayers of bromoethylphosphate-, phosphorylcholine-, phosphorylethanolamine-, hydroxyl-terminated polymers or self-assembling monolayers, poly(carboxybetaine methacrylate) polymer, or polystyrene coated with a copolymer of L-histidine, a zwitterion, *n*-butyl methacrylate and hydrophobic moiety; polymer brushes containing sulfated carbohydrate repeat units resembling surface-tethered heparin; polysaccharide-based glycocalyx-mimicking polymer coating; free ϵ -amino surface groups incorporated using PEG-lysine conjugates; polyurethane coated with a lysine-derivatized acrylamide polymer; nanocomposite fibrinolytic coatings comprising proteolytic enzymes tethered to the surfaces of carbon nanotubes and dispersed in poly (methyl methacrylate), enzymes such as serine protease, subtilisin Carlsberg and trypsin, the enzymes being loaded onto the carbon nanotubes by physisorption and a fibrinolytic enzyme being optionally incorporated into the coatings; a low-leaching, NO-generating polyelectrolyte multilayer thin film comprising sodium alginate and organoselenium-modified polyethyleneimine prepared by layer-by-layer assembly on a silicone rubber or polyurethane substrate; polyelectrolyte multilayer coatings of chitosan and dextran sulfate on poly (tetramethylene adipate-*co*-terephthalate, L-arginine being optionally incorporated; polyurethane coatings incorporating hyaluronic acid as a chain extender during polyurethane synthesis; poly (ester urethane) dip-coated with an amphiphilic conjugate of stearyl poly (ethylene oxide) with 4,4'-methylene diphenyl diisocyanate, a film-building additive in the form of a polytetramethylene glycol-based polyurethane elastomer being incorporated; polymer coatings of paracyclophane derivatives

co-deposited in controlled ratios by chemical vapour deposition as functionalized coatings polymerized into poly (*p*-xylenes) during the deposition process; heparin immobilized on silicone via a heterobifunctional PEG spacer; treatments of said valving element including doping (fluorine doped DLC) or the provision of functionalized endgroups (PU) for attachment of a variety of compounds; said coatings and said treatments or any combination of them also being applied as required to said supporting ring and to said stent.

70. The prosthetic valve of Claim 18 in which said valving element is collapsed into compact form for endovascular implantation by restraining said annular supporting ring while rotational tension is applied to said valving element via said capping piece such that the coils of said valving element assume a compact, tightly-nested, conical form; a force then being applied to said annular supporting ring at a point diametrically opposed to the point of attachment of said valving element such that said supporting ring is completely collapsed inwardly against the opposing side allowing the ends of the collapsed form to be overlapped, said collapsed form of said valve being less than half its normal diameter; said collapsed valve then being fixed in correct directional orientation within the distal end of a suitable expandable stent which is, itself, collapsed into compact form; said stent and said valve then being drawn into a thin metal sleeve supported on the distal end of a catheter with a deflated balloon within said stent.

71. The prosthetic valve of Claim 1 in which said valving element is fixed to said annular supporting ring by means of a peg formed on the end of said valving element, said peg being permanently accommodated within a complementary bore in a boss formed on said annular supporting ring.

72. The prosthetic valve of Claim 1 which is elastically compliant, radial pressure applied to the closed said valving element being accommodated by sliding displacement of its said turns one to another without their being unseated.

73. The prosthetic valve of Claim 1 in which, depending upon the elastic characteristics of the particular material from which said valving element is made, said turns of said valving element are made with a thickness in the range 0.01 millimetre to 4.0 millimetres.

74. The prosthetic valve of Claim 1 in which said valving element is made in

composite or laminated form with one or more layers of a soft flexible material laminated with one or more layers of a stiffly flexible material, the thickness and width of said layers being varied to provide desired physical characteristics.

- 5 75. The prosthetic valve of Claim 1 in which said valving element is made from a thin, superelastic metal, such as nitinol, the superelastic characteristics of said material being exploited to permit said valve to be collapsed into compact form to facilitate implantation.
- 10 76. The prosthetic valve of Claim 1 in which the local width and thickness of said turns of said valving element are adjusted to ensure a consistent elastic response to pressure-generated forces throughout all parts of said valving element.
77. The prosthetic valve of Claim 1 in which said valving element is made with a greater or lesser number of turns to suit the needs of a particular application, the number of turns varying between 1 and 10.
- 15 78. The prosthetic valve of Claim 1 in which, to facilitate implantation of said valve, said valving element is collapsed into compact form by winding it around and along a thin cylinder.
79. The prosthetic valve of Claim 1 in which, in order to manipulate flow characteristics through a said valve and in zones adjacent it, the cross-sectional shaping of said valving element is locally varied.
- 20 80. The prosthetic valve of Claim 1 in which the first turn of said valving element and/or said annular supporting ring to which it is attached are made thicker and narrower and shaped to facilitate flow past them.
81. The prosthetic valve of Claim 1 in which the degree of overlap of said turns of said valving element is varied at different parts of said valving element, a consistent seating force being achieved throughout said valving element by increasing overlap in turns of larger diameter and decreasing overlap in turns of smaller diameter, reduced overlap being acceptable in turns of smaller diameter owing to their greater positional stability.
- 25 82. The prosthetic valve of Claim 1 in which deflected leading and trailing edges of successive said turns of said valving element are made to nest closely.
- 30 83. The prosthetic valve of Claim 1 in which the end of the first turn of said valving element is supported from said annular supporting ring by one or more thin,

narrow elastic elements, the ends of which are embedded securely in said valving element and in said annular supporting ring, said elastic elements being accommodated in complementary channels formed in the upper surface of said supporting ring; said elastic elements being free to rise upwardly from said channels and their free length being such as to permit the fixed end of said valving ring to rise clear of said annular supporting ring, thereby ensuring that the attachment zone of said valving element and said supporting ring is continuously swept by blood and that stagnation does not occur; in the closed position of said valve, the end of said valving element just contacting the slightly angled end surface of a rebate provided in said annular supporting ring.

84. The prosthetic valve of Claim 83 in which said elastic elements take the form of highly polished, elastic, round metal wire.

85. The prosthetic valve of Claim 1 in which, to minimise thrombogenic effects, said valving element is made with its surfaces covered in a biological material, such as fibrous pericardium.

86. The prosthetic valve of Claim 1 in which said capping piece is made hollow from a suitable softly flexible material and is able to be collapsed for endovascular implantation, said capping piece being inflated after implantation by a slow chemical reaction generating a settable polymer foam.

87. The prosthetic valve of Claim 1 in which a narrow, slightly raised, annular sealing surface is provided along the surfaces of said valving element, said raised sealing surface being situated medially on both surfaces of said turns or at the outer edge of the lower surfaces of said turns or the inner edge of the upper surfaces of said turns.

88. The prosthetic valve of Claim 1 in which said valving element and said annular supporting ring are formed in a single piece, said combined components being formed using a suitable 3D forming process and subsequently heated or subjected to another densification process.

89. A method of replacing a venous or cardiac valve comprising implantation of a prosthetic valve comprising a valving element in the form of a plurality of spirally-arranged, partially overlapping and facially abutting layers, said valving element being made in a single piece from a thin, elastic material, the end of its

outer turn being fixed to an annular supporting ring and the end of its final turn terminating in a capping piece which acts as a central closure of said layers; in their collapsed, abutting state, said partially overlapping layers acting to provide a complete obstruction to flow in one direction but, when pressure is applied to them from the counter direction, lifting and elastically separating in a mode similar to that of the coils of a very light spring; opening of said valve involving only a small torsional distortion distributed more or less equally throughout the whole length of said valving element, said valving element incorporating no hinges or other mechanical components which might be subject to impact damage or frictional wear, the distributed nature of said spirally-arranged aperture of the open said valve providing a large effective aperture.

90. The method of Claim 89 in which said annular supporting ring is fixed to and supported in a tubular stent, a circumferential band of the material of said annular supporting ring extending through said stent and sealingly cooperating with the inner wall surface of a vessel in which said stent is implanted.

91. The method of Claim 89 in which said prosthetic valve is implanted in a vessel by first being collapsed into a compact form and inserted into a carrier tube positioned on the end of a catheter; said carrier tube being introduced into said vessel and positioned as required using said catheter; said valve then being ejected from said carrier tube and permitted to elastically expand into place or is expanded into place by means of a balloon.

92. The method of Claim 89 in which, in order to provide a more streamlined flow of blood through said valve, said turns of said valving element are made tapered - arranged in the form of a shallow cone - and with the leading (upstream) and trailing (downstream edges) of each said turn deflected to be parallel to the local flow.

93. The method of Claim 89 in which said annular supporting ring and said stent are deleted and the end of the lower turn of said valving element is fixed to a fixation band or sewing ring as incorporated into prosthetic heart valves of conventional arrangement.

94. The method of Claim 89 in which said valving element is supported from an annular supporting ring supplanting the aortic valve at the base of the ascending

aorta, said supporting ring being provided at its upper, outer circumference with an upwardly and outwardly curving fillet which acts to maintain streamlined flow and prevent the pooling of blood in that zone; said supporting ring having formed on its lower edge a downward and outwardly curving collar which passes
5 beneath and effectively encloses the aortic annulus, said collar acting to maintain a streamlined flow and prevent the pooling of blood in that zone; radially arranged sutures being inserted through said supporting ring to secure it permanently in place, suitably positioned pairs of apertures being provided in said supporting ring to accommodate said sutures, said pairs of apertures being
10 joined at their inner ends by narrow, shallow channels which accommodate suture loops passing between said pairs of apertures and maintain said loops flush with the inner surface of said supporting ring.

95. The method of Claim 89 in which, in order to provide a more streamlined flow of blood through said valve, said edges of said valving element are deflected
15 towards the axis of the aorta and said deflected edges are locally modified to generate a three-dimensional, helical blood flow pattern within said ascending aorta similar in character to that of the natural flow pattern.

96. The method of Claim 94 in which said prosthetic valve is installed in the supra-annular position using a sewing ring of more or less conventional arrangement
20 incorporated into said annular supporting ring.

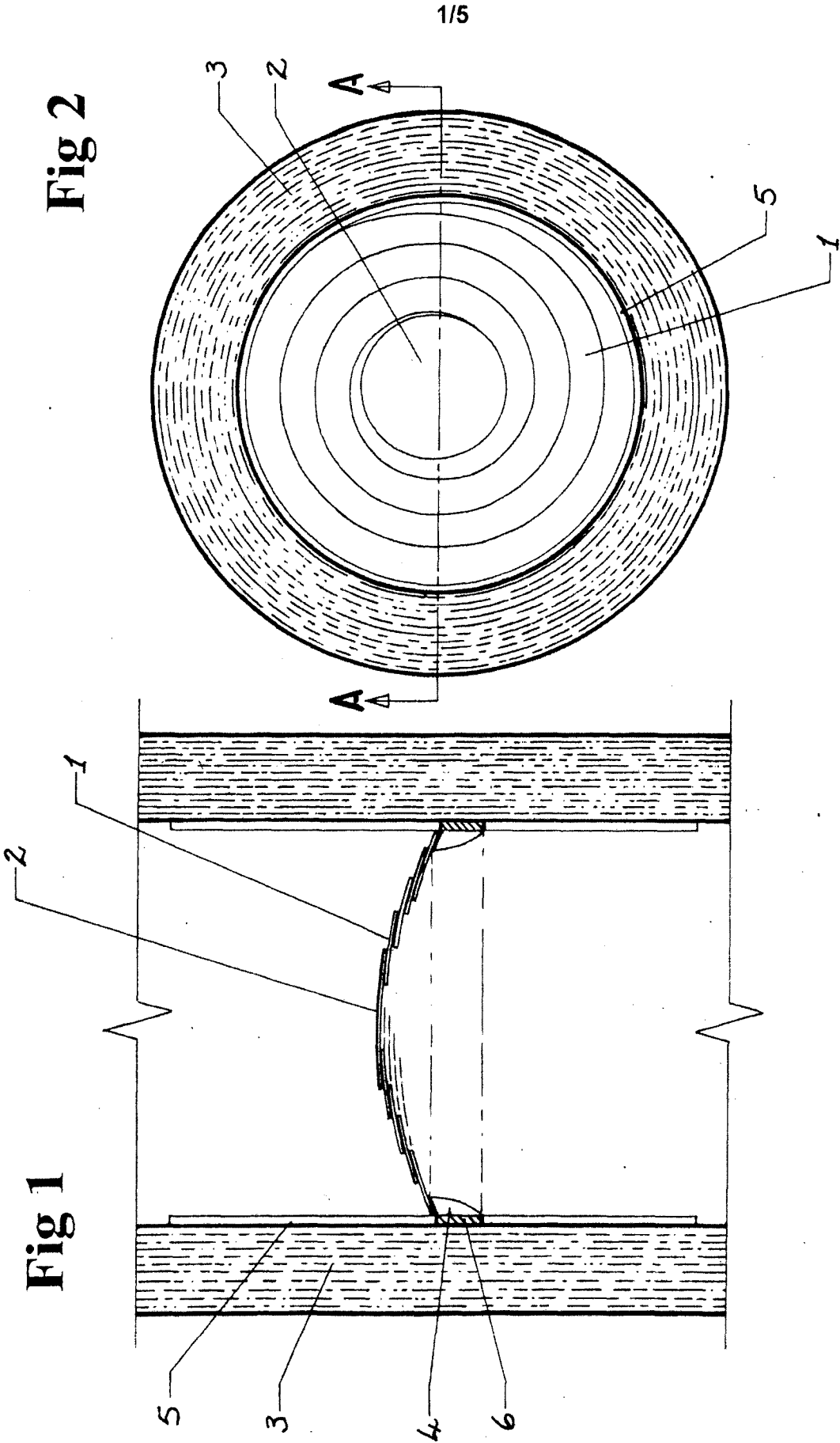
97. The method of Claim 94 in which said valve is installed in the ascending aorta.

98. The method of Claim 89 in which said valve is implanted in a vessel via a longitudinal incision, said valve and its said annular supporting ring being inserted through said incision, positioned and secured by a plurality of
25 circumferentially arranged sutures; said sutures being passed through pairs of suitable, radially arranged apertures and tied against an external restraining band of suitable, non-elastic material, shallow channels being provided in the inner surface of said supporting ring joining each said pair of apertures, said channels accommodating said sutures and maintaining them more or less flush with the
30 internal surface of said supporting ring.

99. The method of Claim 89 in which said valving element is collapsed into compact form for endovascular implantation by restraining said annular supporting ring

while rotational tension is applied to said valving element via said capping piece such that the coils of said valving element assume a compact, tightly-nested, conical form; a force then being applied to said annular supporting ring at a point diametrically opposed to the point of attachment of said valving element such that said supporting ring is completely collapsed inwardly against the opposing side, allowing the ends of the collapsed form to be overlapped, said collapsed form of said valve being less than half its normal diameter; said collapsed valve then being fixed in correct directional orientation within the distal end of a suitable expandable stent which is, itself, collapsed into compact form; said stent and said valve then being drawn into a thin metal sleeve supported on the distal end of a catheter with a deflated balloon within said stent.

100. The method of Claim 89 in which the end of the first turn of said valving element is supported from said annular supporting ring by one or more thin, narrow elastic elements, the ends of which are embedded securely in said valving element and in said annular supporting ring, said elastic elements being accommodated in complementary channels formed in the upper surface of said supporting ring; said elastic elements being free to rise upwardly from said channels and their free length being such as to permit the fixed end of said valving ring to rise clear of said annular supporting ring, thereby ensuring that the attachment zone of said valving element and said supporting ring is continuously swept by blood and that stagnation does not occur; in the closed position of said valve, the end of said valving element just contacting the slightly angled end surface of a rebate provided in said annular supporting ring.



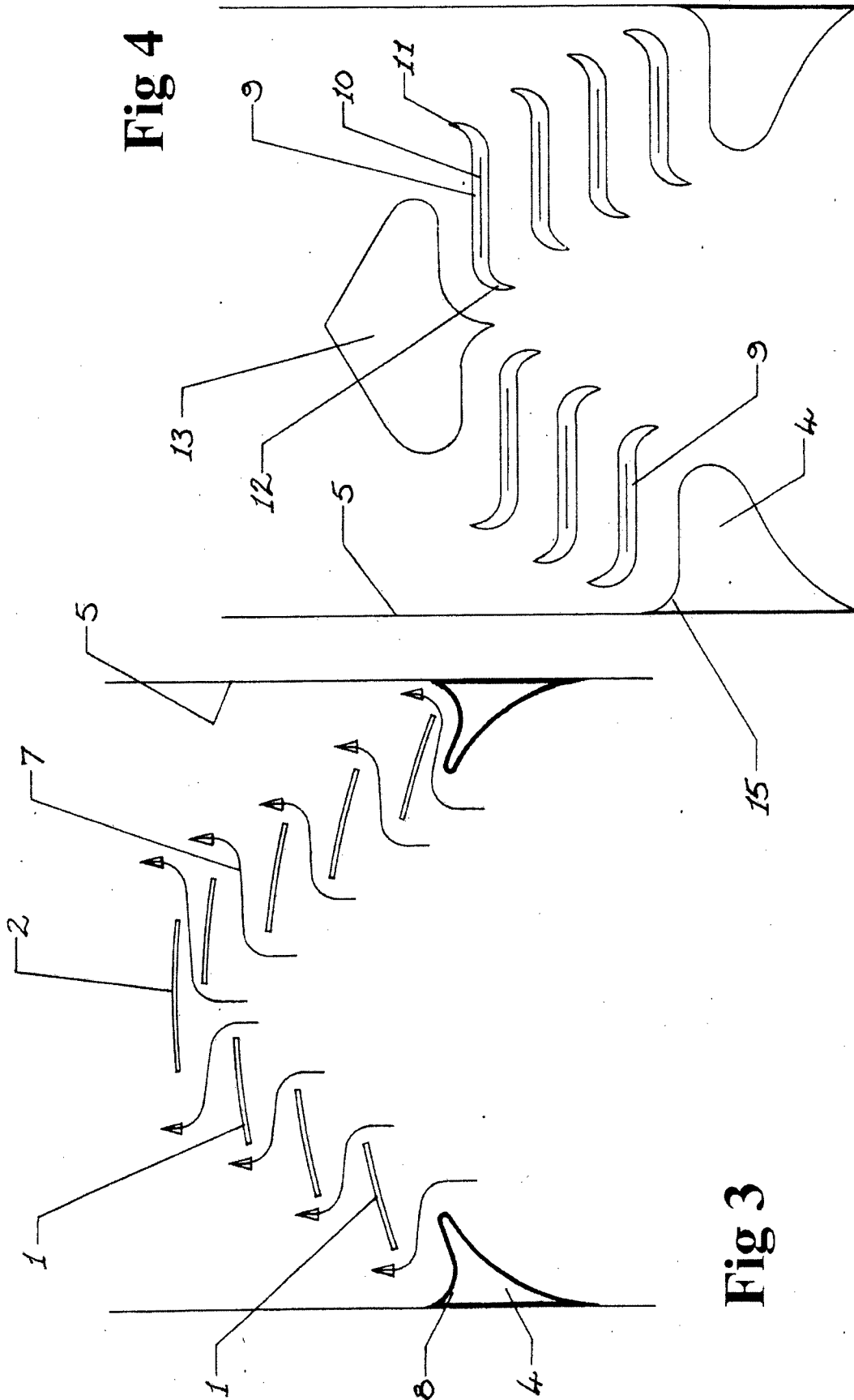
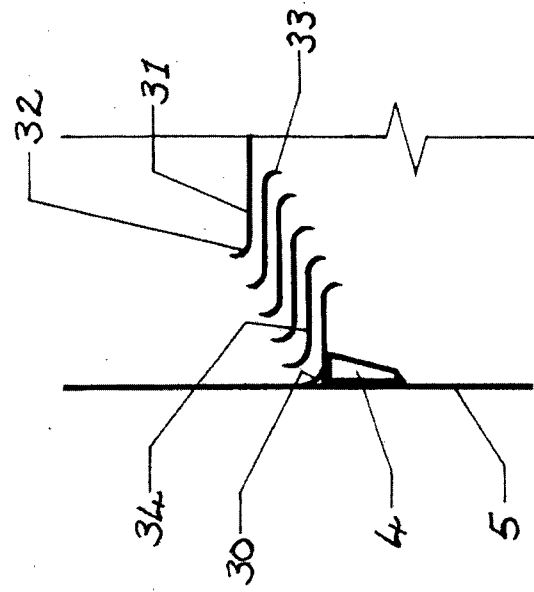
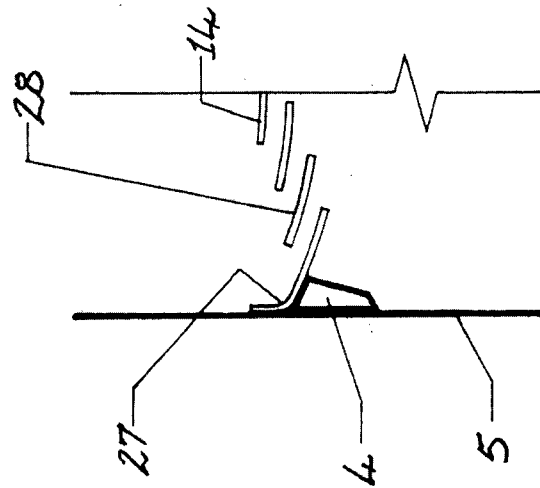
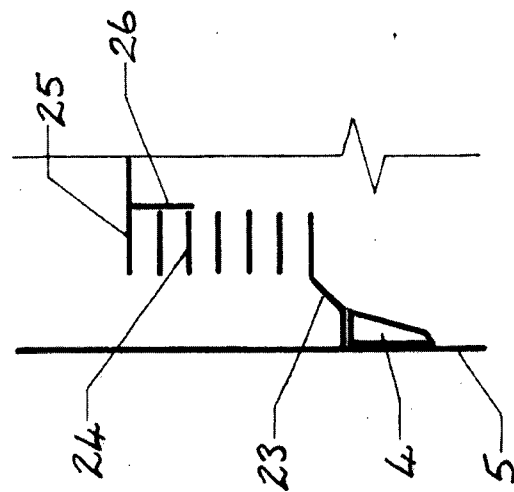
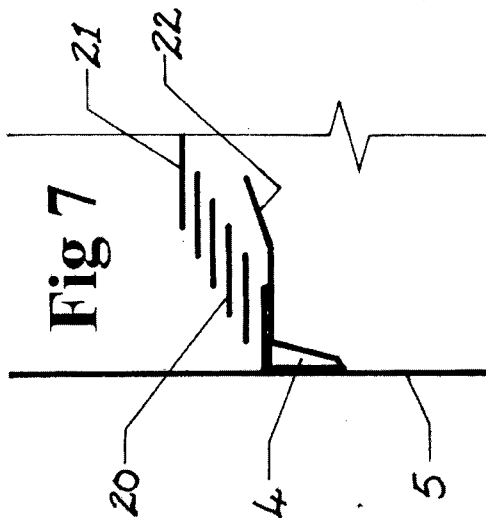
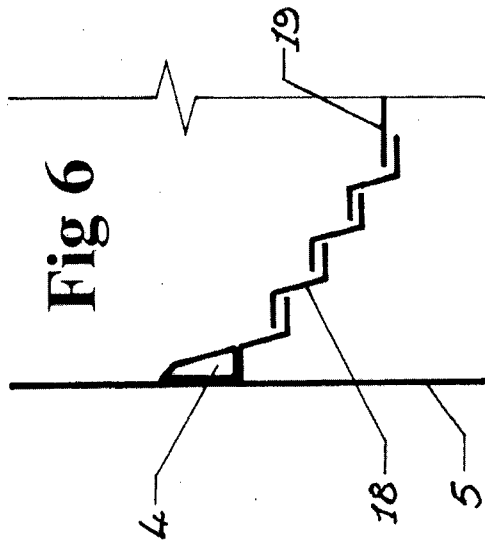
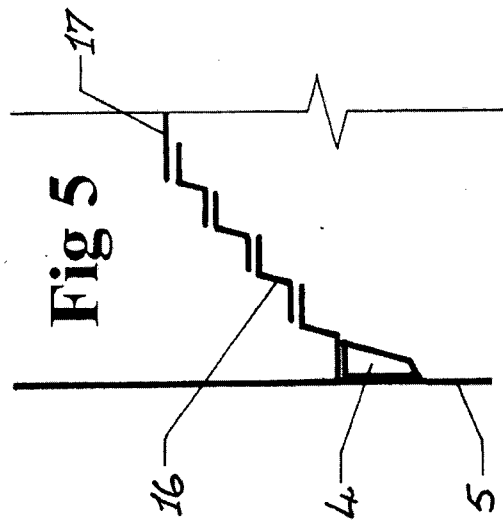


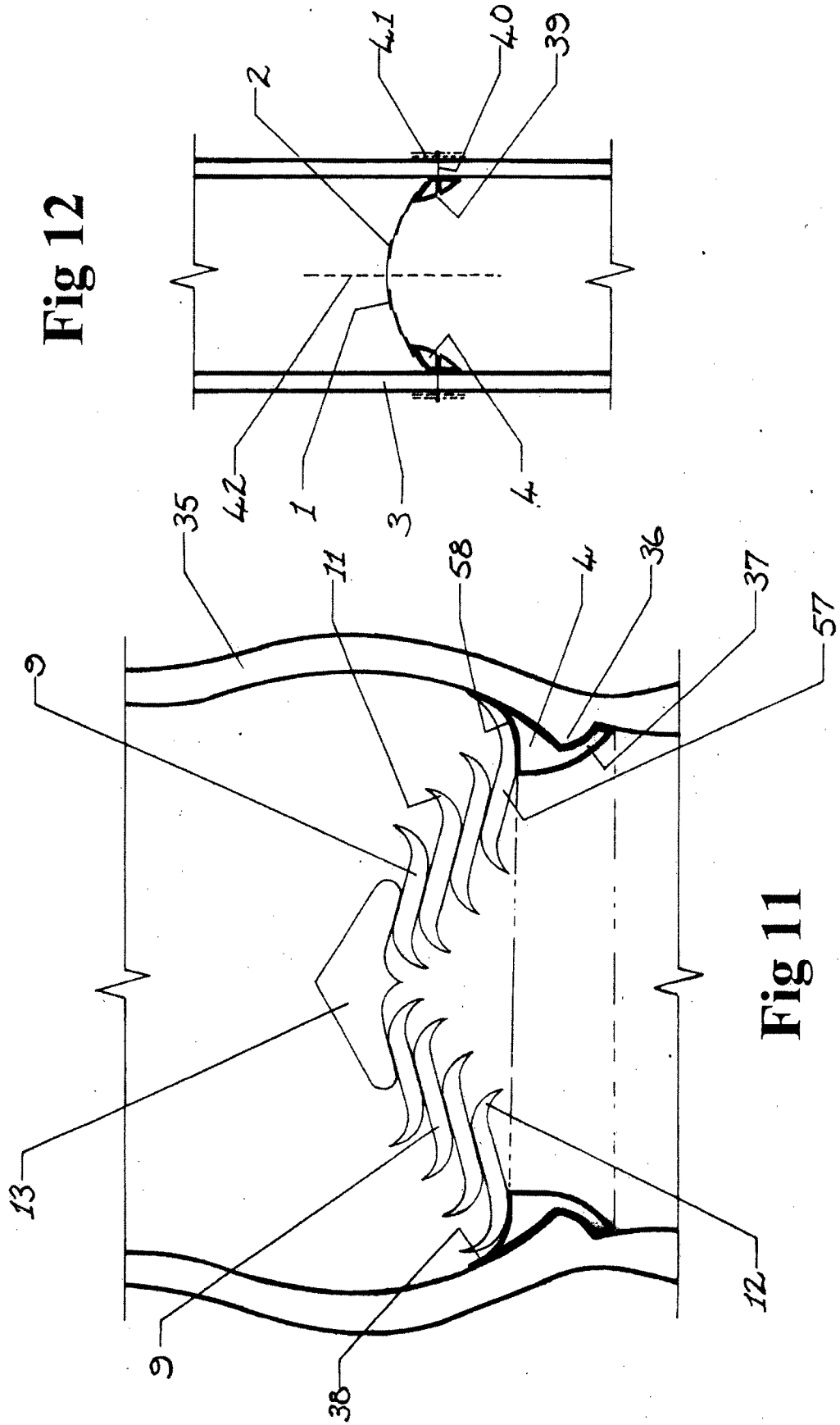
Fig 4

Fig 3



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Fig 12



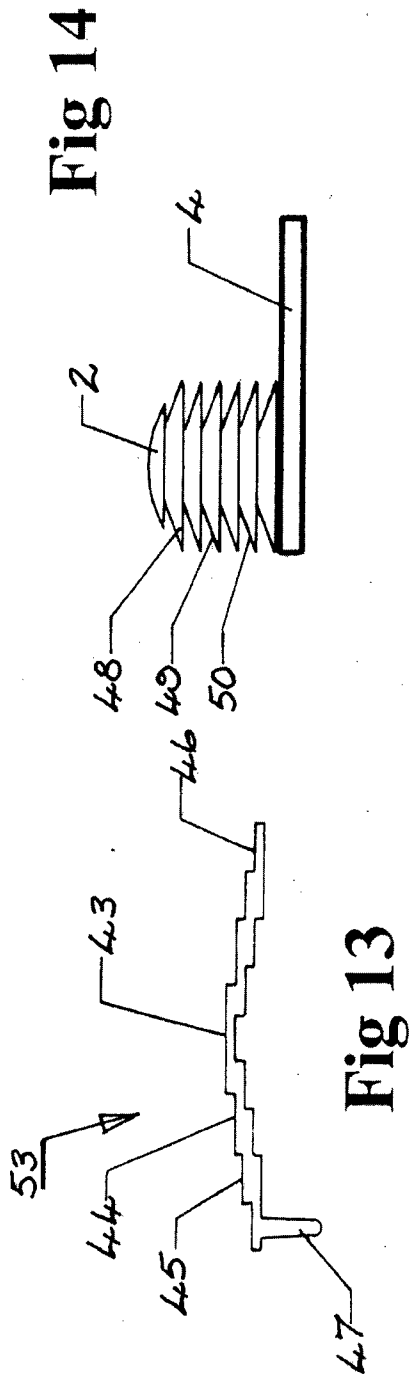


Fig 14

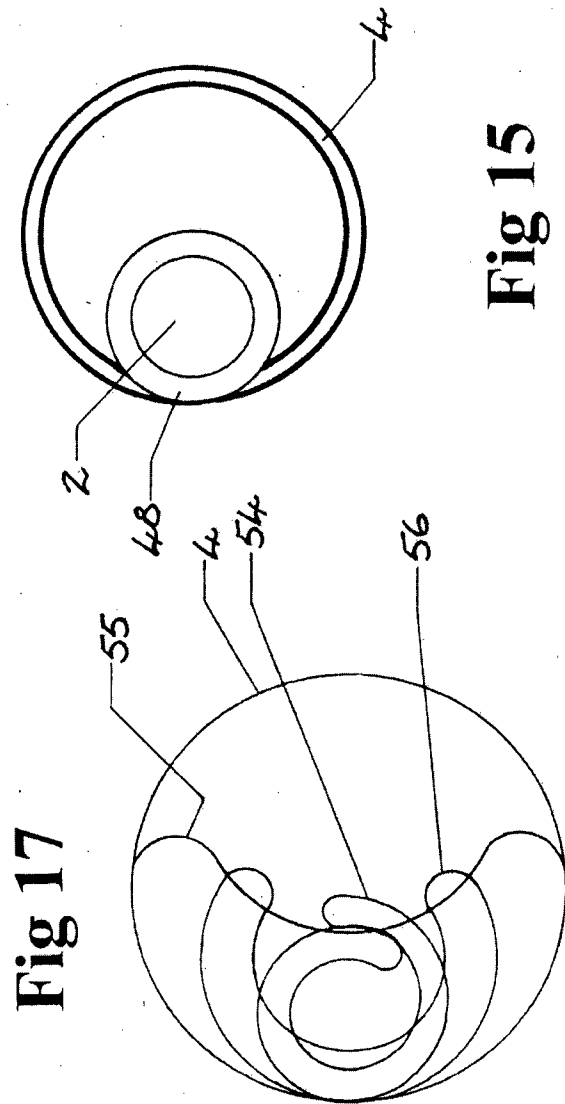
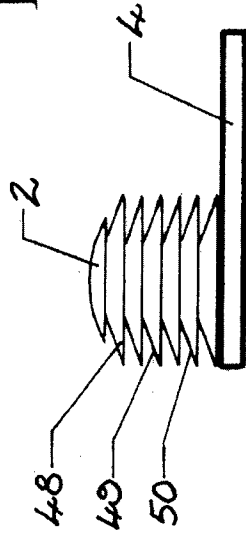
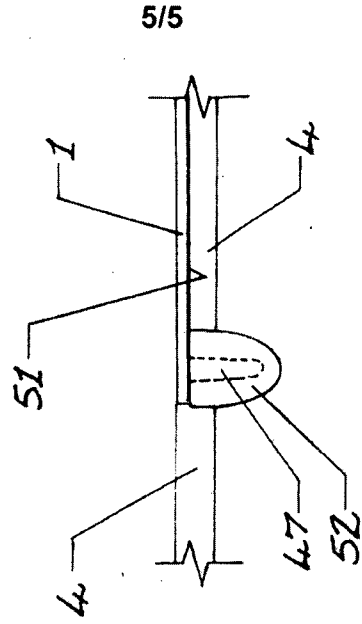
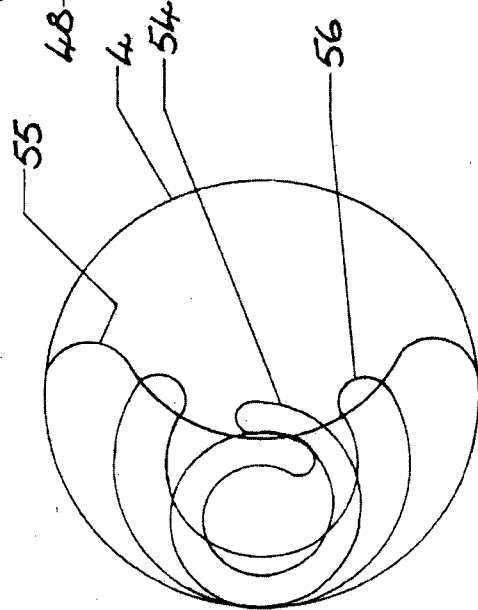


Fig 17



INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2012/001104**A. CLASSIFICATION OF SUBJECT MATTER****A61F 2/24 (2006.01)**

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI and EPODOC and A61F 2/24, 2/06 and keywords: valve and spiral and elastic and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	



Further documents are listed in the continuation of Box C



See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
12 November 2012Date of mailing of the international search report
12 November 2012**Name and mailing address of the ISA/AU**

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INTERNATIONAL SEARCH REPORT		International application No.
C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		PCT/AU2012/001104
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Information on patent family members		PCT/AU2012/001104	
This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.			
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