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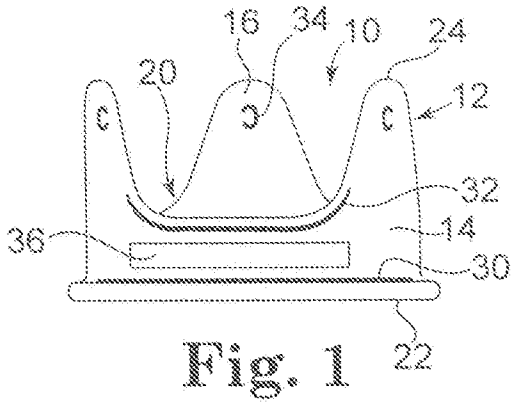

Fig. 1

(57) Abstract: A replacement prosthetic heart valve (10) for engagement with a structure of an original prosthetic heart valve that includes at least one visually detectable marker. The replacement heart valve includes a stent structure (14) having a generally tubular body portion and at leastjone visually detectable marker 830, 32, 34) on a portion of the stent structure, and at least two leaflets attached within the interior area of the tubular body portion of the stent structure. At least one visually detectable marker of the stent structure is alignable with at least one visually detectable marker of the original prosthetic heart valve.

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MARKERS FOR PROSTHETIC HEART VALVES

TECHNICAL FIELD

The present invention relates to prosthetic heart valves. More particularly, it relates to devices, methods, and delivery systems for percutaneously implanting prosthetic heart valves.

BACKGROUND

Diseased or otherwise deficient heart valves can be repaired or replaced using a variety of different types of heart valve surgeries. Typical heart valve surgeries involve an open-heart surgical procedure that is conducted under general anesthesia, during which the heart is stopped while blood flow is controlled by a heart-lung bypass machine. This type of valve surgery is highly invasive and exposes the patient to a number of potentially serious risks, such as infection, stroke, renal failure, and adverse effects associated with use of the heart-lung machine, for example.

Recently, there has been increasing interest in minimally invasive and percutaneous replacement of cardiac valves. Such surgical techniques involve making a very small opening in the skin of the patient into which a valve assembly is inserted in the body and delivered to the heart via a delivery device similar to a catheter. This technique is often preferable to more invasive forms of surgery, such as the open-heart surgical procedure described above. In the context of pulmonary valve replacement, U.S. Patent Application Publication Nos. 2003/0199971 A1 and 2003/0199963 A1, both filed by Tower, et al., describe a valved segment of bovine jugular vein, mounted within an expandable stent, for use as a replacement pulmonary valve. The replacement valve is mounted on a balloon catheter and delivered percutaneously via the vascular system to the location of the failed pulmonary valve and expanded by the balloon to compress the valve leaflets against the right ventricular outflow tract, anchoring and sealing the replacement valve. As described in the articles: "Percutaneous Insertion of the Pulmonary Valve", Bonhoeffer, et al., Journal of the American College of

Cardiology 2002; 39: 1664 – 1669 and "Transcatheter Replacement of a Bovine Valve in Pulmonary Position", Bonhoeffer, et al., Circulation 2000; 102: 813 – 816, the replacement pulmonary valve may be implanted to replace native pulmonary valves or prosthetic pulmonary valves located in valved conduits. Various types and configurations of prosthetic heart valves are used in percutaneous valve procedures to replace diseased natural human heart valves. The actual shape and configuration of any particular prosthetic heart valve is dependent to some extent upon the valve being replaced (i.e., mitral valve, tricuspid valve, aortic valve, or pulmonary valve). In general, the prosthetic heart valve designs attempt to replicate the function of the valve being replaced and thus will include valve leaflet-like structures used with either bioprostheses or mechanical heart valve prostheses. In other words, the replacement valves may include a valved vein segment that is mounted in some manner within an expandable stent to make a stented valve. In order to prepare such a valve for percutaneous implantation, the stented valve can be initially provided in an expanded or uncrimped condition, then crimped or compressed around the balloon portion of a catheter until it is as close to the diameter of the catheter as possible. Other percutaneously-delivered prosthetic heart valves have been suggested having a generally similar configuration, such as by Bonhoeffer, P. et al., "Transcatheter Implantation of a Bovine Valve in Pulmonary Position." Circulation, 2002; 102:813-816, and by Cribier, A. et al. "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis." Circulation, 2002; 106:3006-3008, the disclosures of which are incorporated herein by reference. These techniques rely at least partially upon a frictional type of engagement between the expanded support structure and the native tissue to maintain a position of the delivered prosthesis, although the stents can also become at least partially embedded in the surrounding tissue in response to the radial force provided by the stent and balloons that are sometimes used to expand the stent. Thus, with these transcatheter techniques, conventional sewing of the prosthetic heart valve to the patient's native tissue is not necessary. Similarly, in an article by Bonhoeffer, P. et al. titled "Percutaneous Insertion of the Pulmonary Valve." J Am Coll Cardiol, 2002; 39:1664-1669, the disclosure of

which is incorporated herein by reference, percutaneous delivery of a biological valve is described. The valve is sutured to an expandable stent within a previously implanted valved or non-valved conduit, or a previously implanted valve. Again, radial expansion of the secondary valve stent is used for placing and maintaining the replacement valve.

Although there have been advances in percutaneous valve replacement techniques and devices, there is a desire to be able to easily and accurately position percutaneously delivered replacement valves within a previously implanted valve. In particular, it would be advantageous to provide a replacement valve and corresponding delivery system that facilitates proper positioning of the replacement valve with respect to certain features of a heart valve that was previously implanted, while viewing the valve from outside the patient's body.

SUMMARY

The prosthetic valves of the invention are configured to provide complimentary features that promote optimal placement of a replacement heart valve within their interior areas. Such a placement of a replacement heart valve can be performed percutaneously or minimally invasively. The features of the invention can be used for aortic valve, mitral valve, pulmonic valve, venous, and/or tricuspid valve replacement. In some embodiments, the replacement heart valves of the invention are highly amenable to transvascular delivery using a transapical approach (either with or without cardiopulmonary bypass and either with or without rapid pacing). The methodology associated with the present invention can be repeated multiple times, such that several prosthetic heart valves of the present invention can be mounted on top of or within one another, if necessary or desired.

The replacement heart valves of the invention each include a compressible stent or frame to which a valve structure is attached. The stents of the invention include a wide variety of structures and features that can be used alone or in combination with features of other stents of the invention. In particular, these stents can be provided with a number of different docking and/or anchoring structures that are conducive to percutaneous delivery thereof. Many of

the structures are thus compressible to a relatively small diameter for percutaneous delivery to the heart of the patient, and then are expandable either via removal of external compressive forces (e.g., self-expanding stents), or through application of an outward radial force (e.g., balloon expandable stents). The delivery systems described herein can be used to deliver stents, valved stents, or other interventional devices such as ASD (atrial septal defect) closure devices, VSD (ventricular septal defect) closure devices, or PFO (patent foramen ovale) occluders.

Methods for insertion of the replacement heart valves of the invention include delivery systems that can maintain the stent structures in their compressed state during their insertion and allow or cause the stent structures to expand once they are in their desired location. In addition, delivery methods of the invention can include features that allow the stents to be retrieved for removal or relocation thereof after they have been deployed or partially deployed from the stent delivery systems. The methods may include implantation of the stent structures using either an antegrade or retrograde approach.

When delivering a replacement valve in accordance with the invention, it is rotatable in vivo to allow the valve to be positioned in a desired orientation. In one embodiment of the invention, a surgically implanted valve is provided with at least one marking or some type of indicia that is radiopaque, echogenic, and/or has some other characteristic that allows it to be viewed from outside the patient's body. The marking or indicia can be provided so that it provides a positive indication of the position and orientation of the stent frame. The replacement stented valve can be provided with markings that correspond to the markings on the surgically implanted valve. The replacement valve can further include a compliant skirt that is designed to function both as a sealing ring and as a visual indicator of the positioning and seating of the valve during and after implantation.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be further explained with reference to the appended Figures, wherein like structure is referred to by like numerals throughout the several views, and wherein:

Figure 1 is a front view of a prosthetic heart valve frame;

Figure 2 is a front view of a replacement stented heart valve;

Figure 3 is a top view of the replacement stented heart valve of Figure 2;

Figure 4 is a front view of the stented valve of Figure 2 positioned relative to the prosthetic valve frame of Figure 1;

Figure 5 is a top view of the valve and valve frame of Figure 4;

Figure 6 is another front view of the stented valve of Figure 2 positioned relative to the prosthetic valve frame of Figure 1;

Figure 7 is a top view of the valve and valve frame of Figure 6;

Figure 8 is a schematic front view of a stent in a first position relative to an aortic valve; and

Figure 9 s a schematic front view of the stent of Figure 8 in a second position relative to an aortic valve.

DETAILED DESCRIPTION

Referring now to the Figures, wherein the components are labeled with like numerals throughout the several Figures, and initially to Figure 1, one embodiment of an exemplary prosthetic heart valve 10 is illustrated. This valve 10 is a typical configuration of a valve that can be implanted within the heart of a patient, such as by suturing or otherwise securing the valve 10 into the area of a native heart valve of a patient. The native heart valves referred to herein can be any of the human heart valves (i.e., mitral valve, tricuspid valve, aortic valve, or pulmonary valve), wherein the type and orientation of an implanted (e.g., surgically implanted) prosthetic heart valve 10 will correspond with the particular form, shape, and function of the native heart valve in which it is implanted. Although valve 10 would typically include multiple leaflets attached within its interior area, such leaflets are not shown in this figure for illustration clarity purposes.

Valve 10 generally includes a valve structure 12 including a stent structure 14 from which multiple stent posts or commissure posts 16 extend. All or a portion of the valve structure 12, including the stent structure 14 and stent

posts 16, can be covered by a flexible covering, which may be a tissue, polymer, fabric, cloth material, or the like to which leaflets (not shown) of the heart valve 10 are attached, such as by sewing. The stent structure 14 may alternatively be a wire form. Further, as is known in the art, the internal structure of each of the stent posts 16 can be formed of a stiff but somewhat resiliently bendable material. This construction allows the stent posts 16 to be moved from the orientation shown in Figure 1 to a deflected orientation by the application of an external force. Once this external force is removed or reduced, the stent posts 16 can then move back toward the orientation shown in Figure 1. Alternatively, the stent posts can be angled at least slightly toward or away from a central axis of the valve 10.

The valve structure 12 is generally tubular in shape, defining an internal area 20 (referenced generally) that extends from an inflow end 22 to an outflow end 24. The internal area 20 is essentially surrounded by the valve structure 12, and the leaflets attached within the valve structure 12 selectively allow for fluid flow into and out of the lumen of the natural heart valve in which it is implanted. That is, the internal area 20 is alternatively open and closed to the lumen of the natural heart valve in which it is inserted via movement of leaflets. In some patients, the prosthetic heart valve 10 will be implanted using typical surgical techniques, whereby the stent ring 14 is sewn or attached to the annulus or valvular rim of the native heart valve. Alternatively, the prosthetic valve can be placed in the patient using minimally invasive techniques for holding the valve in place, such as U-clips, for example, or a wide variety of other techniques and features used for minimally invasive and/or percutaneous implantation of the initial prosthetic heart valve.

The prosthetic heart valves (e.g., heart valve 10 and replacement valve 50 that will be discussed below) used in accordance with the devices and methods of the invention may include a wide variety of different configurations, such as a prosthetic heart valve that has tissue leaflets, or a synthetic heart valve that has polymeric leaflets. In this way, the heart valves can be specifically configured for replacing any heart valve. That is, while much of the description herein refers to replacement of aortic valves, the stents (and their associated leaflets) of the

invention can also generally be used for replacement of tricuspid valves, for use as a venous valve, or to replace a failed bioprosthesis, such as in the area of an aortic valve or mitral valve, for example. The replacement prosthetic heart valves of the present invention can be employed to functionally replace stentless prosthetic heart valves as well.

Referring again to Figure 1, heart valve 10 further includes a number of markers that can help to facilitate accurate placement of a replacement heart valve within the valve structure 12, such as when the originally implanted heart valve 10 becomes deficient and needs to be replaced. In particular, heart valve 10 is provided with at least one annular marker 30 that can extend along one or more portions or the entire annular portion of a valve, at least one sinus marker 32 for placement at the sinus opening, and at least one commissure marker 34 that can be used for locating of one or more commissure posts.

In this exemplary embodiment, commissure marker 34 has a curved "c" shape, which is a directional marker that can help the clinician in determining the location of the post and also in determining whether the stent post is facing toward or away from the viewing direction. In other words, each marker 34 can advantageously be configured to be distinctly different or opposite when viewed from the front and back, due to its shape or configuration. In addition, the markers 34 are preferably made of a material that allows them to be viewed from the opposite surface of the stent post from the surface on which the marker 34 is placed (i.e., "through" the stent post) when using certain imaging techniques. Due to the directional nature of the markers, these indicia would therefore be displayed backwards or as a mirror image of the original marker when viewed from the opposite side of the commissure post. However, it is contemplated that the marker 34 will not be visible to the unassisted eye in this "backward" orientation, but that it will only be visible in this orientation when using specific visualization equipment. It is further contemplated that the marker(s) can extend through the entire thickness of the stent or that the marker(s) are provided in some other way so that they are visible from both sides, even without visualization equipment. Figure 1 shows an arrangement where two of the "c" shaped markers 34 are facing forward and one of the "c" shaped markers 34 is shown as being backward

because it is actually being viewed through the commissure post 16. The marker 34 can instead be a different letter of the alphabet, a number, a symbol, a shape, or some other indicia or combination of different indicia. It is preferred, however, that the indicia is easily distinguishable as having a front view or position and a reverse view or position. It is further contemplated that different commissure posts 16 have a different marker or indicia so that each of the commissure posts 16 are also visually distinguishable from each other. Another marker 36 can also be provided to indicate the location in which the replacement valve 10 can "seal" into the original valve. Marker 36 can be a strip or area that is positioned generally adjacent to the member 32, as shown, and the valve 10 may include a marker 36 adjacent to each of the markers 32. That is, marker 36 may comprise multiple marker strips spaced from each other around the circumference of the valve 10, or may comprise a single continuous strip that extends all or most of the entire circumference of the valve 10. A single valve may include some or all of these different types and positions of markers.

The marker or markers provided on the heart valve can be made of a radiopaque material and/or have echogenic or other properties so that they are visible from outside the patient's body when using an appropriate imaging technique. The markers may be made of platinum iridium, tungsten, barium sulfate, other radiopaque materials, and the like. In this way, the markers can be used to view the movement of the valve while it is being implanted in the patient and can also be used to verify correct positioning of the valve.

After some period of time, it may become desirable to place or implant a replacement prosthetic heart valve relative to a previously implanted prosthetic heart valve to functionally replace the older heart valve. This may occur in cases where it is determined that a previously implanted prosthetic heart valve is functionally deficient due to one or more of a variety of factors, such as stenosis, valve failure, structural thrombosis, inflammation, valve insufficiency, and/or other medical conditions. Regardless of the cause of the deficiency, rather than removing the previously implanted prosthetic heart valve and implanting a second, similarly configured prosthetic heart valve via relatively complicated and invasive open heart surgical techniques, the methods and devices of the present

invention leave the deficient previously implanted prosthetic heart valve in place (e.g., heart valve 10), and deploy a replacement heart valve so that it functionally replaces the previously implanted prosthetic heart valve. Prior to implanting the replacement valve, the leaflets of the previously implanted and deficient prosthetic heart valve can either be removed using a variety of techniques such as cutters, lasers, and the like, or the leaflets may instead be left in place within the deficient valve, where they will likely be pushed toward the walls of the vessel upon implantation of the replacement valve.

One or more markers on the valve, along with a corresponding imaging system (e.g., echo, MRI, etc.) can be used with the various repositionable delivery systems described herein in order to verify the proper placement of the valve prior to releasing it from the delivery system. A number of factors can be considered, alone or in combination, to verify that the valve is properly placed in an implantation site, where some exemplary factors are as follows: (1) lack of paravalvular leakage around the replacement valve, which can be advantageously examined while blood is flowing through the valve since these delivery systems allow for flow through and around the valve; (2) optimal rotational orientation of the replacement valve relative to the coronary arteries; (3) the presence of coronary flow with the replacement valve in place; (4) correct longitudinal alignment of the replacement valve annulus with respect to the native patient anatomy; (5) verification that the position of the sinus region of the replacement valve does not interfere with native coronary flow; (6) verification that the sealing skirt is aligned with anatomical features to minimize paravalvular leakage; (7) verification that the replacement valve does not induce arrhythmias prior to final release; and (8) verification that the replacement valve does not interfere with function of an adjacent valve, such as the mitral valve.

Figures 2 and 3 illustrate one exemplary embodiment of a replacement valve 50, which generally includes a stent 52 and a valve structure 54 positioned within and attached to the stent 52. The valve 50 further includes a sealing skirt 62 adjacent to one end that extends generally around the outer periphery of the stent 52. In general, the stents described herein include a support structure comprising a number of strut or wire portions arranged relative to each other to

provide a desired compressibility and strength to the heart valve. Other details of various configurations of the stents of the invention are also described below; however, in general terms, stents of the invention are generally tubular support structures, and a valve structure will be secured with this support structure to make a stented valve.

Some embodiments of the support structures of the stents described herein can be a series of wires or wire segments arranged so that they are capable of transitioning from a collapsed state to an expanded state. The stents may further include a number of individual wires formed of a metal or other material that comprise the support structure. These wires are arranged in such a way that allows for folding or compressing to a contracted state in which the internal stent diameter is greatly reduced from when it is in an expanded state. In its collapsed state, such a support structure with attached valves can be mounted over a delivery device, such as a balloon catheter, for example. The support structure is configured so that it can expand when desired, such as by the expansion of the balloon catheter. The delivery systems used for such a stent should be provided with degrees of rotational and axial orientation capabilities in order to properly position the new stent at its desired location.

The wires of the support structure of the stents in other embodiments can alternatively be formed from a shape memory material such as a nickel titanium alloy (e.g., Nitinol). With this material, the support structure is self-expandable from a contracted state to an expanded state, such as by the application of heat, energy, or the like, or by the removal of external forces (e.g., compressive forces provided by a sheath). This support structure can typically be repeatedly compressed and re-expanded without damaging the structure of the stent. In one embodiment of the invention, the stent 52 is made of a series of wires that are compressible and expandable through the application and removal of external forces, and may include a series of Nitinol wires that are approximately 0.011-0.015 inches in diameter, for example. The support structure of the stents may be laser cut from a single piece of material or may be assembled from a number of different components. For these types of stent structures, one example of a system that can be used for delivery thereof includes a catheter with

a retractable sheath that covers the stent until it is to be deployed, at which point the sheath can be retracted to allow the stent to expand.

Valve structure 54 includes multiple leaflets 56 that are attached to stent features 58. Some or all of stent features 58 further include a stent marking or indicia 60, which will be discussed in further detail below. The stent features 58 may be a separate component that is secured within the stent, or the stent features 58 may actually be the general area where two leaflet pieces that are sewn to the stent form a "peak" or commissure area. The valve structures shown and described relative to the Figures are generally configured to accommodate multiple leaflets and replace a heart valve (e.g., heart valve 10) that has a corresponding number of commissure posts for a multiple-leaflet structure. The replacement prosthetic heart valves of the invention will generally include three leaflets, but can incorporate more or less than three leaflets. As referred to herein, the replacement heart valves may include a wide variety of different configurations, such as a replacement heart valve having tissue leaflets or a synthetic heart valve having polymeric, metallic, or tissue-engineered leaflets, and can be specifically configured for replacing any heart valve.

The leaflets of the valves can be formed from a variety of materials, such as autologous tissue, xenograph material, or synthetics as are known in the art. The leaflets may be provided as a homogenous, biological valve structure, such as a porcine, bovine, or equine valve. Alternatively, the leaflets can be provided independent of one another (e.g., bovine or equine pericardial leaflets) and subsequently assembled to the support structure of the stent. In another alternative, the stent and leaflets can be fabricated at the same time, such as may be accomplished using high strength nano-manufactured NiTi films produced at Advanced Bio Prosthetic Surfaces (ABPS) of San Antonio, Texas, for example. In more general terms, the combination of a support structure with one or more leaflets for a replacement heart valve can assume a variety of other configurations that differ from those shown and described, including any known prosthetic heart valve design. In certain embodiments of the invention, the support structure with leaflets can be any known expandable prosthetic heart valve configuration, whether balloon expandable, self-expanding, or unfurling (as described, for

example, in U.S. Patent Nos. 3,671,979; 4,056,854; 4,994,077; 5,332,402; 5,370,685; 5,397,351; 5,554,185; 5,855,601; and 6,168,614; U.S. Patent Application Publication No. 2004/0034411; Bonhoeffer P., et al., "Percutaneous Insertion of the Pulmonary Valve", Pediatric Cardiology, 2002; 39:1664-1669; Anderson H R, et al., "Transluminal Implantation of Artificial Heart Valves", EUR Heart J., 1992; 13:704-708; Anderson, J. R., et al., "Transluminal Catheter Implantation of New Expandable Artificial Cardiac Valve", EUR Heart J., 1990, 11: (Suppl) 224a; Hilbert S. L., "Evaluation of Explanted Polyurethane Trileaflet Cardiac Valve Prosthesis", J Thorac Cardiovascular Surgery, 1989; 94:419-29; Block P C, "Clinical and Hemodyamic Follow-Up After Percutaneous Aortic Valvuloplasty in the Elderly", The American Journal of Cardiology, Vol. 62, Oct. 1, 1998; Boudjemline, Y., "Steps Toward Percutaneous Aortic Valve Replacement", Circulation, 2002; 105:775-558; Bonhoeffer, P., "Transcatheter Implantation of a Bovine Valve in Pulmonary Position, a Lamb Study", Circulation, 2000:102:813-816; Boudjemline, Y., "Percutaneous Implantation of a Valve in the Descending Aorta In Lambs", EUR Heart J, 2002; 23:1045-1049; Kulkinski, D., "Future Horizons in Surgical Aortic Valve Replacement: Lessons Learned During the Early Stages of Developing a Transluminal Implantation Technique", ASAIO J, 2004; 50:364-68; the teachings of which are all incorporated herein by reference).

Figures 4-7 illustrate the positioning of a replacement valve 50 within the internal area 20 of heart valve 10. For illustration purposes, a portion of the stent structure 14 is removed so that that the internal area of the heart valve 10 can be viewed more clearly; however, the stent structure 14 will typically be a continuous ring structure that has previously been implanted in a patient. In one embodiment of the invention, the replacement valve 50 is delivered percutaneously to the area of the heart valve 10. If the valve 50 includes a balloon-expandable stent, this can include providing a transcatheter assembly, including a delivery catheter, a balloon catheter, and a guide wire. Some delivery catheters of this type are known in the art, and define a lumen within which the balloon catheter is received. The balloon catheter, in turn, defines a lumen within which the guide wire is slideably disposed. Further, the balloon catheter includes

a balloon that is connected to an inflation source. It is noted that if the stent being implanted is a self-expanding type of stent, the balloon would not be needed and a sheath or other restraining means would be used for maintaining the stent in its compressed state until deployment of the stent, as described herein. In any case, for a balloon-expandable stent, the transcatheter assembly is appropriately sized for a desired percutaneous approach to the implantation location. For example, the transcatheter assembly can be sized for delivery to the heart valve via an opening at a carotid artery, a jugular vein, a sub-clavian vein, femoral artery or vein, or the like. Essentially, any percutaneous intercostals penetration can be made to facilitate use of the transcatheter assembly.

Prior to delivery, the replacement stent is mounted over the balloon in a contracted state to be as small as possible without causing permanent deformation of the stent structure. As compared to the expanded state, the support structure is compressed onto itself and the balloon, thus defining a decreased inner diameter as compared to its inner diameter in the expanded state. While this description is related to the delivery of a balloon-expandable stent, the same basic procedures can also be applicable to a self-expanding stent, where the delivery system would not include a balloon, but would preferably include a sheath or some other type of configuration for maintaining the stent in a compressed condition until its deployment.

With the stent mounted to the balloon, the transcatheter assembly is delivered through a percutaneous opening (not shown) in the patient via the delivery catheter. The implantation location is located by inserting the guide wire into the patient, which guide wire extends from a distal end of the delivery catheter, with the balloon catheter otherwise retracted within the delivery catheter. The balloon catheter is then advanced distally from the delivery catheter along the guide wire, with the balloon and stent positioned relative to the implantation location. In an alternative embodiment, the stent is delivered to an implantation location via a minimally invasive surgical incision (i.e., non-percutaneously). In another alternative embodiment, the stent is delivered via open heart/chest surgery.

As described above, the heart valve 10 includes one or more markers 30, 32, 34, and/or 36, and the replacement valve 50 includes one or more radiopaque, echogenic, or MRI visible markers 60 to facilitate visual confirmation of proper placement of the replacement valve 50. The valve 50 may further include one or more markers 64, each of which extends generally along a portion of the belly of a leaflet, such as leaflet 56. In addition, the sealing skirt 62 can itself have echogenic or detectable properties for alignment with features of a heart valve 10. Further, although one of the markers 34 is shown in Figures 4 and 6 as an inverted "C" shape, this marker would only be visible in this configuration when using visualization techniques for detecting this marker (e.g., fluoroscopic visualization techniques and equipment), since it would not otherwise be visible to the eye through the tissue of the valve 50. Thus, in order to implant a replacement valve 50, it can be advanced using a delivery system or other surgical device and methods to the internal area 20 of the heart valve 10, One or more of the imaging techniques discussed above can then be used to orient and accurately position the replacement valve 50, where one such technique is illustrated with continued reference to Figures 4-7.

As shown in Figures 4 and 5, none of the stent post markers 60 are aligned with the commissure markers 34 on the heart valve 10. Thus, the replacement valve 50 is not optimally oriented and can be rotated by the delivery system, for example, until the stent post markers 60 are aligned with the commissure markers 34, as is illustrated in Figures 6 and 7, and as can be verified using an imaging system that makes these markers visible to the operator of the valve delivery system. The delivery system is preferably capable of orienting the replacement valve rotationally and in a longitudinal direction relative to the heart valve in which it will be positioned. The other markers provided on the heart valve 10 can also be observed relative to markers on the replacement valve 50 to verify the proper orientation of the valve 50 relative to the valve 10. In addition or alternatively, a marker 64 of the replacement valve 50 can be aligned with a sinus marker 32 of the valve 10 and/or a marker zone 62 of the replacement valve 50 can be aligned with an annular marker 30 and/or marker 36 of the heart valve 10. In one embodiment, one or more of the markers 60, 62, 64 of the replacement

valve 50 can be aligned with respective markers of the heart valve 10 (e.g., markers 34, 36, 32, respectively). Alternatively, any combination of one or more markers can be used for alignment of replacement valve 50 with features of heart valve 10.

Orientation and positioning of the replacement stented valves may be accomplished either by self-orientation of the stents (such as by interference between features of the stented valve and a previously implanted stent or valve structure) or by manual orientation of the stented valve to align its features with anatomical or previous bioprosthetic features, such as can be accomplished using fluoroscopic visualization techniques, for example. For example, when aligning the stented valves of the invention relative to native anatomical structures, they should be aligned so as to not block the coronary arteries, and native mitral or tricuspid valves should be aligned relative to the anterior leaflet and/or the trigones/commissures.

While one exemplary embodiment of a replacement valve is described above, it is understood that the stent of the replacement valve can have a structure that is at least somewhat different than that illustrated in Figure 2. That is, stent can have the same or a different number of crowns at its opposite ends, and/or the center portion can have a more or less dense concentration of wires than either of the ends. The stent may further include a central bulbous region between the first and second ends that has a larger diameter than the first and second ends of the stent. The bulbous region can be configured to generally match the contours of the anatomy where the stent will be positioned in the patient (e.g., at the aortic valve sinus region). The stent may alternatively or additionally include flared portions that extend from opposite sides of the central portion. Such a stent may be positioned within the anatomy (e.g., the aorta) of a patient so that the flares extend into the adjacent ventricle in order to help anchor the stent in place but so that they do not disrupt the native anatomical function.

It can be advantageous for the stent delivery process that the replacement valve is retractable or partially retractable back into a sheath at any point in the process until the stent is disengaged from the delivery system. This can be useful for repositioning of the stent if it is determined that the stent has

been improperly positioned relative to the patient's anatomy and/or the prosthetic heart valve into which it is being delivered. In this case, the steps described above can be repeated, using the markers as desired, until the desired positioning of the replacement valve is achieved.

Another embodiment of the invention is illustrated in Figures 8 and 9 with a stent 100 positioned relative to an aorta 120, coronary arteries 122, and native aortic valve leaflets 124. The stent 100 is generally tubular in shape and includes a series of generally flexible wires or wire segments arranged so that the stent is capable of transitioning from a collapsed state to an expanded state. The valve that would be positioned within the stent is not illustrated in these figures; however, such a valve with leaflets would be attached within the stent to provide a stented valve.

Stent 100 is illustrated as having a larger diameter at its inflow end 102 and a compliant skirt 104 positioned in the transition area between the larger and smaller diameter portions of the stent. The compliant skirt 104 preferably extends around all or most of the periphery of the stent 100 and is designed to function as either or both a sealing ring for the stent 100 and as a visual indicator of the positioning of the stent relative to the anatomy in which it is being implanted. The skirt 104 can alternatively or additionally be provided with anchoring features such as tissue ingrowth coatings or hooks that help minimize paravalvular leakage and promote anchoring of the stent 100. The skirt 104 is further provided to facilitate positioning of the implant with respect to the patient's anatomy. The skirt 104 is therefore provided with radiopaque properties, echogenic properties, and/or other visualization properties, and can be made from a fabric, polymer, wire, mesh material, gel material, or combination thereof, for example. Any of these materials can be provided with various radiopaque properties and/or additives so that the skirt 104 is viewable using chosen imaging techniques and equipment. The markers can be uniformly dispersed throughout the skirt or may alternatively or additionally be located at specific valve features such as commissures, leaflets, and the like. The skirt 104 may be made of a porous or a non-porous material. The skirt 104 is also provided with an initial shape and size

that will require it to be deformed at least slightly when the stent is properly positioned relative to its target location.

As shown, the native valve leaflets 124 have been pushed toward the walls of the aorta 120 by the structure of the stent 100 as it has been positioned using some type of delivery system, such as one of the types of delivery systems discussed above. Figure 8 illustrates an initial positioning of the stent relative to a landing zone 106. When the stent 100 is in this position, the skirt 104 is not yet in contact with the annulus of the aortic valve and the leaflets 124. The stent 100 is then moved closer to the annulus of the aorta until the skirt 104 contacts the annulus, as is shown in Figure 9, which thereby causes the compliant skirt 104 to deform. In order to provide a uniform seal around annulus, it is preferable that all or most of the periphery of the skirt 104 deforms at least slightly when it is pressed against the annulus. The circumferential positioning of the skirt 104 also provides the clinician with the ability to identify whether or not the replacement stented valve is seated normal to the longitudinal axis of the aorta 120 to thereby minimize the chances for paravalvular leakage, heart block, and/or migration. The deformation of the compliant skirt 104 therefore preferably provides a positive visual indication of the correct placement and proper axial rotational alignment of the stent.

The skirt 104 may be provided with a specific shape and/or size that can be measured and/or quantified in its initial condition. A target amount of deformation can be determined for optimal placement of the stent in the anatomy so that the clinician can visually detect when the skirt 104 has deformed by that predetermined amount, wherein this amount of deformation will provide the desired placement of the stent relative to the implantation site. As shown, the skirt 104 has a generally circumferential configuration; however, skirt 104 can take a wide variety of shapes. For one example, the skirt 104 can be scalloped and/or have cut-out portions to generally match the three-dimensional shape of the native valve annulus. Additionally, it is contemplated that a stent can include multiple skirts in order to achieve additional sealing and/or to provide additional indications to the clinician of the placement, including axial and/or rotational alignment of the stent.

The present invention has now been described with reference to several embodiments thereof. The entire disclosure of any patent or patent application identified herein is hereby incorporated by reference. The foregoing detailed description and examples have been given for clarity of understanding only. No unnecessary limitations are to be understood therefrom. It will be apparent to those skilled in the art that many changes can be made in the embodiments described without departing from the scope of the invention. Thus, the scope of the present invention should not be limited to the structures described herein, but only by the structures described by the language of the claims and the equivalents of those structures.

CLAIMS

What is claimed is:

1. A replacement prosthetic heart valve for engagement with a structure of a an original prosthetic heart valve that comprises at least one visually detectable marker, the replacement heart valve comprising:

a stent structure comprising:

a generally tubular body portion; and

at least one visually detectable marker on a portion of the stent structure; and

at least two leaflets attached within the interior area of the tubular body portion of the stent structure;

wherein the at least one visually detectable marker of the stent structure is positionable relative to at least one visually detectable marker of the original prosthetic heart valve.

2. The replacement heart valve of claim 1, wherein at least one visually detectable marker of the replacement heart valve is directionally distinguishable.

3. The replacement heart valve of claim 2, wherein at least one visually detectable marker of the replacement heart valve is c-shaped.

4. The replacement heart valve of claim 2, wherein at least one visually detectable marker of the original heart valve is directionally distinguishable.

5. The replacement heart valve of claim 4, wherein the at least one marker of the replacement heart valve comprises indicia that is the same as the at least one marker of the original heart valve.

6. The replacement heart valve of claim 1, wherein at least one of the visually detectable markers is visible with fluoroscopic visualization techniques.

7. The replacement heart valve of claim 1, wherein the at least one visually detectable marker of the replacement heart valve comprises at least one skirt that extends around at least a portion of the generally tubular body portion.

8. The replacement heart valve of claim 7, wherein the at least one skirt comprises a deformable sealing skirt, wherein deformation of the sealing skirt is visually detectable.

9. The replacement heart valve of claim 1, wherein the at least one visually detectable marker of the replacement valve comprises multiple markers.

10. A replacement prosthetic heart valve in combination with an original heart valve, wherein the original valve comprises at least one visually detectable marker and wherein the replacement heart valve comprises at least one visually detectable marker that is alignable with the at least one marker of the original heart valve.

11. The combination of claim 10, wherein the at least one visually detectable marker of the original heart valve comprises at least one of an annular marker, a one sinus marker, and a commissure marker.

12. The combination of claim 11, wherein the original heart valve comprises at least one annular marker, at least one sinus marker, and at least one commissure marker.

13. The combination of claim 11, wherein the original heart valve comprises at least one annular marker, and wherein the at least one visually detectable marker of the replacement heart valve comprises at least one skirt marker for alignment with the at least one annular marker of the original heart valve.

14. The combination of claim 11, wherein the at least one visually detectable marker of the replacement heart valve comprises at least one commissure marker for alignment with at least one commissure marker of the original heart valve.

15. The combination of claim 10, wherein the at least one visually detectable marker of the replacement valve comprises at least one deformable sealing skirt, wherein deformation of the sealing skirt is visually detectable.

16. A replacement heart valve comprising:

a stent structure comprising:

a generally tubular body portion; and

at least one visually detectable deformable skirt surrounding at least a portion of the tubular body portion; and

at least two leaflets attached within the interior area of the tubular body portion of the stent structure;

wherein the at least one deformable skirt is deformable in response to pressure of the skirt against a native valve annulus.

17. A method of implanting a replacement prosthetic heart valve within an original prosthetic heart valve comprising at least one visually detectable marker, the method comprising:

positioning a replacement prosthetic heart valve in an internal area defined by a generally tubular structure of the original prosthetic heart valve, wherein the replacement heart valve comprises:

a stent structure comprising:

a generally tubular body portion; and

at least one visually detectable marker on a portion of the stent structure; and

at least two leaflets attached within the interior area of the tubular body portion of the stent structure;

adjusting the location of the replacement heart valve by aligning at least one visually detectable marker of the replacement heart valve with at least one visually detectable marker of the original heart valve.

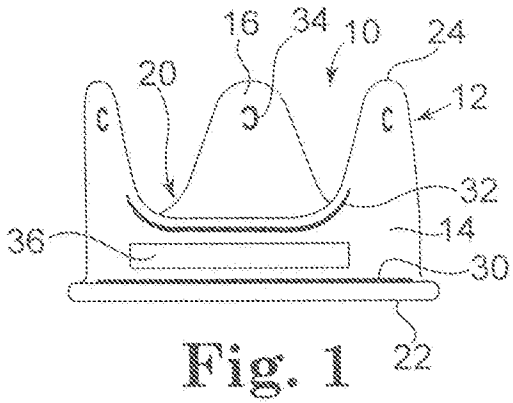

Fig. 1

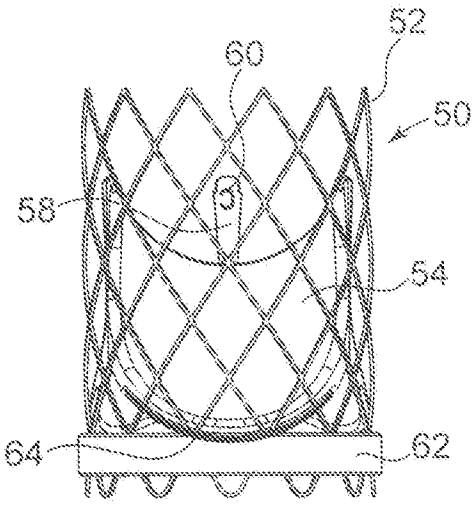

Fig. 2

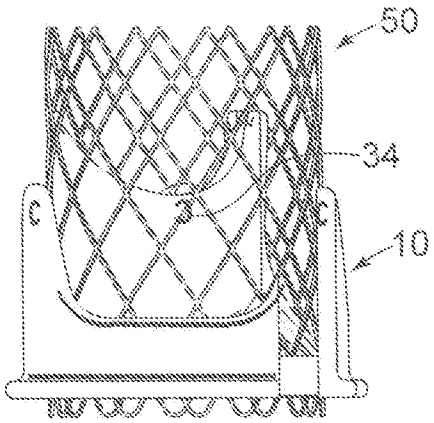

Fig. 4

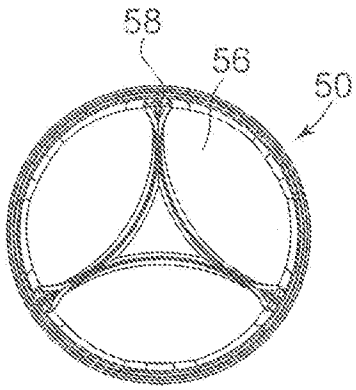

Fig. 3

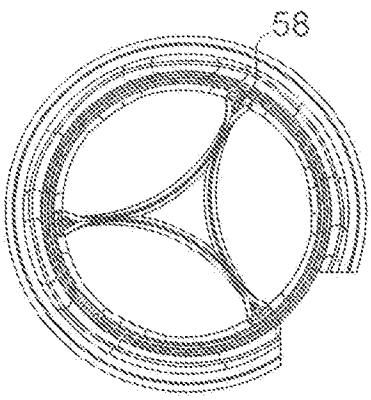

Fig. 5

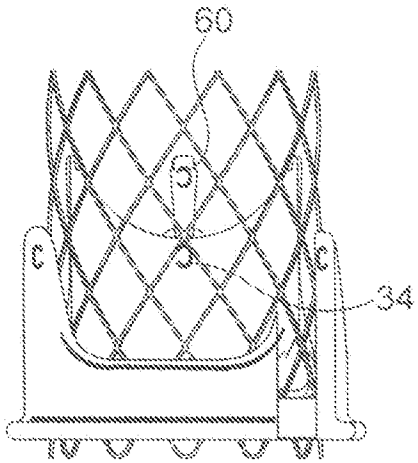

Fig. 6

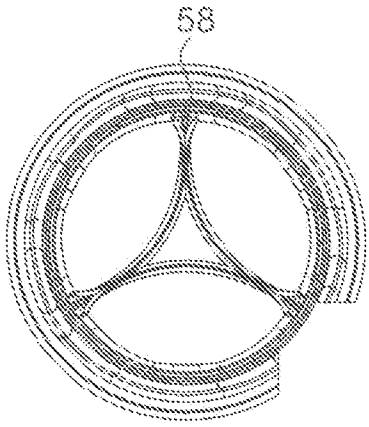

Fig. 7

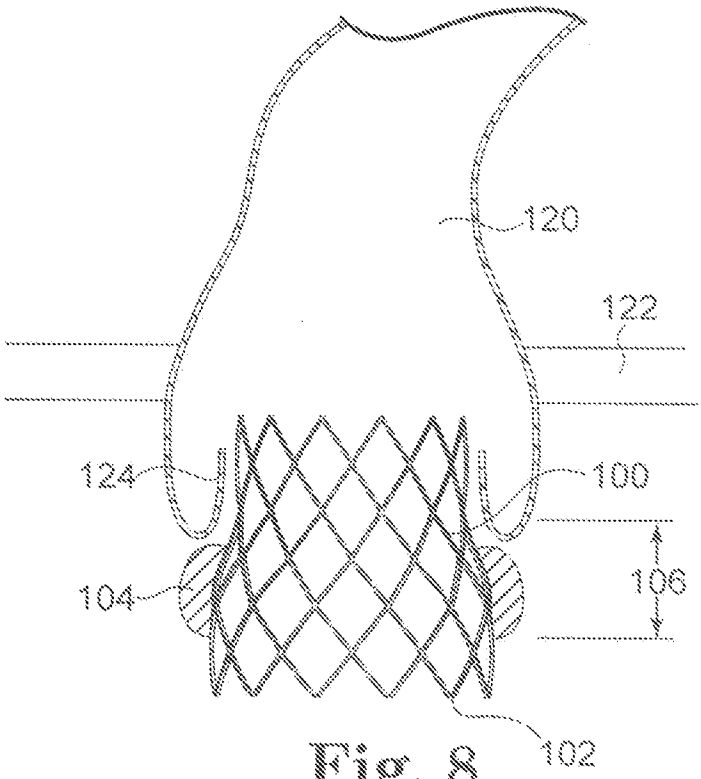

Fig. 8

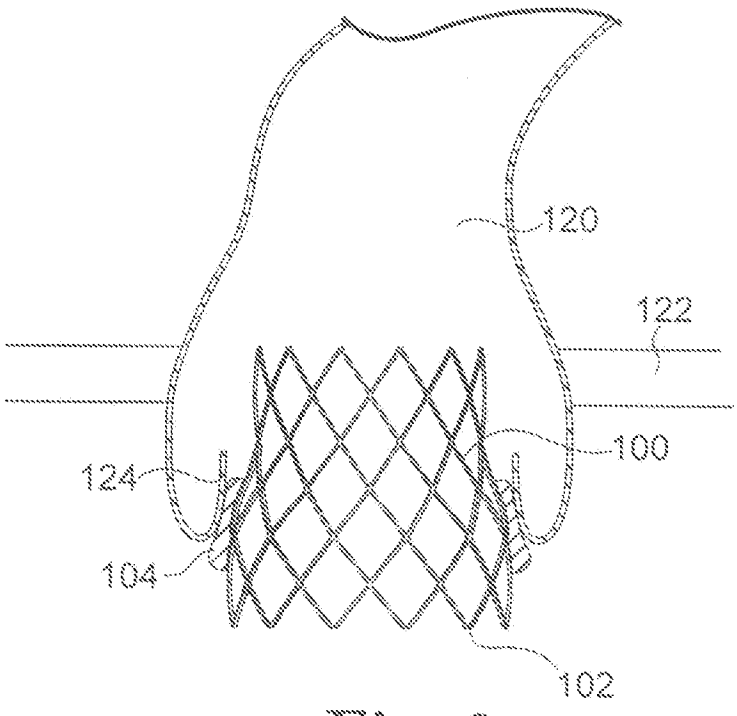

Fig. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/031768

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24

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)
A61F

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2007/130537 A (CHILDRENS MEDICAL CENTER [US]; LOCK JAMES E [US]; MCELHINNEY DOFF B [U) 15 November 2007 (2007-11-15) paragraphs [0010], [0011], [0013], [0014], [0060], [0078]; claim 6; figures 8,9,15	1,2,4-6, 9-12,14
X	WO 01/47438 A (EDWARDS LIFESCIENCES CORP [US]) 5 July 2001 (2001-07-05) page 4, line 1 - page 5, line 10 page 8, line 3 - page 10, line 2 page 11, lines 3-11 figures 1,3,6	1,2,4, 6-16

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[X] Further documents are listed in the continuation of Box C.

[X] 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

"E" earlier document but published on or after the international filing date

"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)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"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

"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.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 March 2009	20/03/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Prechtel, A

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/031768

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 554 990 A (MEDTRONIC INC [US]) 20 July 2005 (2005-07-20) paragraphs [0028], [0057], [0058]; claims 13-15; figure 2	1,2,4-8, 10-13, 15,16
X	US 2006/195184 A1 (LANE ERNEST [US] ET AL) 31 August 2006 (2006-08-31) paragraphs [0007], [0011], [0016], [0097], [0186]; figures 17A,17B	1,2,4-16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/031768

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 17
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/031768

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007130537 A	15-11-2007	CA 2651281 A1	15-11-2007
		EP 2015709 A1	21-01-2009
WO 0147438 A	05-07-2001	AU 2435801 A	09-07-2001
		DE 60032256 T2	14-06-2007
		EP 1239795 A1	18-09-2002
EP 1554990 A	20-07-2005	NONE	
US 2006195184 A1	31-08-2006	AU 2006218877 A1	08-09-2006
		CA 2603198 A1	08-09-2006
		EP 1858451 A1	28-11-2007
		JP 2008531201 T	14-08-2008
		WO 2006093795 A1	08-09-2006