

within the aforementioned sphere to further deter the passage of embolic through the mesh.

[0042] In another preferred embodiment, illustrated in FIG. 2A, provided is an embolic filter 14 which, instead of having a spherical shape as exemplified in FIGS. 2B and 3, has a first end comprising at least one lobe-like formation and a second end which tapers inward therefrom. To make this embodiment, a piece of tubular mesh of suitable length, for example, is swaged at a first end by a first fastener 30. This first fastened end is then pushed into the lumen of the tubular mesh to form lobes 29. The second end of the mesh is then swaged by a second fastener 32. This embodiment is attached to frame 12 by securing first fastener in the lumen of base 16, and securing second fastener 32 in the lumen of base 18. As discussed above, fasteners 30 and 32 are collars having central lumens. The lumens of the collars are substantially aligned along a common longitudinal axis, and dimensioned to receive a guide wire 40.

[0043] In another preferred embodiment, illustrated in FIG. 5A, provided is an embolic filtering device 10, similar to those embodiments described above, but having right anchors 24 which are specifically designed to engage the perimeter of the tissue defining the right-atrial opening 23 of the patent foramen ovale, as illustrated in FIG. 5B. Contrary to right anchors 24 discussed in the aforementioned figures, the ends of right anchors 24 of this embodiment reside against or adjacent to the outside of the tissue wall defining the patent foramen ovale. Right anchors 24 are, therefore, preferably of slightly longer dimension and at least slightly arcuate in shape to facilitate this methodology. The ends of right anchors 24 in this embodiment, include protective caps 27 at their distal ends. Caps 25 can be composed of rubber, plastic, or any other suitable material for covering the ends of anchors 27, and may also comprise radiopaque materials, for example, in order to allow post-implant visualization of the location and positioning of anchors 24 after implant.

[0044] It will be recognized by those of ordinary skill that the manner in mesh 14 can be manufactured in a variety of ways without departing from the scope of the invention. For example, it will be recognized that mesh 14 does not necessarily need to be spherical, or have both an interior and exterior embolic portion, as discussed above. Mesh 14 can be of any shape and dimension suitable to deter the passage of embolic material between a venous blood pool and an arterial blood pool, and can include any number of layers, so long as the interstices between the strands forming mesh 14 are of sufficient area to filter emboli.

[0045] The design and dimensions of frame 12 can also be manufactured in a variety of ways without departing from the scope of the invention. FIGS. 6A and 6B illustrate yet a further embodiment of the invention, wherein arms 20 and 22 are effectively decoupled from one another, such that the tissue distension function of embolic filtering device 10 is provided separately by each individual legs of the device. This allows embolic filtering device 10 to be more compact, and to better fill gaps and meet the contours of the patent foramen ovale. Particularly with respect to the embodiments shown in FIG. 6A and 6B, should be recognized that the size of mesh 14 need not be large, but can cover only arms 20 and 22 and still be effective in treating patent foramen ovals.

[0046] Device 10 provides distinct advantages and improvements over known patent-foramen ovale-treatment

devices. First, the elasticity and ball-like structure of mesh 14, enables device 10 to treat a patent foramen ovals, or other septal defects, of any shape and dimension with equal effectiveness. This is because mesh 14 is compressible along its entire length. Thus, it does not matter if the patent foramen ovale is fenestrated, as the elasticity of mesh 10 will allow it to conform to the substantially exact shape and dimension of the patent foramen ovale. Mesh 14 can also be annealed to have a 3-dimensional to help fill any gaps within the patent foramen ovale space. Thus, the post-implant leakage along the perimeter of known devices caused by their inability to accommodate irregular shaped defects is eliminated. Second, device 10 has substantially less surface compared to known devices, thereby reducing the risk of dangerous blood clot formation on the exterior of the device. Third, contrary to known devices which do not prevent passage of emboli through the defect until tissue growth onto the device occludes the defect, the interstices between the stands of braided mesh 14 of the present invention are small enough to effectively filter emboli as soon as device 10 is implanted. Thus, device 10 offers immediate protection against the passage of emboli at the moment of implant.

[0047] The embolic filtering device 10 is particular useful in preventing the passage of emboli between an venous blood pool and an arterial blood pool. For purposes of exemplary illustration, the method of the invention is herein exemplified through discussion of a method of treating a patent foramen ovale (PFO). However, it should be recognized that the invention can be used to prevent the passage of emboli between any septal defect and/or arterial venous blood pool and arterial blood pool. To deliver the embolic filtering device 10 of the patent foramen ovale, embolic filtering device 10 is loaded into a delivery system 41 comprising a catheter 42, exemplified in FIG. 4. In a preferred embodiment, the embolic filtering device 10 is loaded onto a guide wire 40 by inserting the guide wire through the lumens of first base 16, the lumens of fasteners 30, 32, and 36, if employing a frame 12 with second base 18, the lumen of second base 18. A pair of forceps 44, as exemplified in FIG. 4, or other grasping device, is used to grasp embolic filtering device 10. In a preferred embodiment, first base 16 has a recess 46 for receiving forceps 44, such that forceps 44 are positioned within recess 46 to more securely grasp embolic filtering device 10, and to deter embolic filtering device 10 from detaching from forceps 44. With embolic filtering device 10 secured by forceps 44 embolic filtering device 10 is pulled into catheter 42. As embolic filtering device 10 is pulled into catheter 42, the force of the catheter walls against first base 16 of frame 12 will force side walls 20 and 22, and left anchors 24 and right anchors 26 inward toward one another. Embolic filtering device 10 will gradually collapse as it is pulled into catheter 42.

[0048] Using catheter 42, embolic filtering device 10 is delivered to the patent foramen ovale, or other passage between a venous blood pool or arterial blood pool, to be treated. In particular, the distal end of catheter 42 is extended through the patent foramen ovale from the right atrial side to the left atrial side. With the distal end of catheter 40 positioned in the left atrium adjacent to the patent foramen ovale, forceps 44 are used to withdraw embolic filtering device 10 from catheter 42. As embolic filtering device 10 is withdrawn, embolic filtering device 10 will gradually expand from its collapsed position and into its memorized