

anchors **24** are of sufficient length to securely engage tissue within and/or adjacent to the septal defect. For example, when treating a patent foramen ovale, right anchors **26** preferably engage tissue within and/or adjacent to the right-atrial opening of the patent foramen ovale. Extending arcuately and/or laterally from the portion of arms **20** and **22** proximate second base **18** are left anchors **26**. Left anchors **26** can be of any shape or formation suitable for delivering embolic filtering device **10** to the desired location and securing it in place; however, it has been found that arcuate or coiled anchors are most suitable for effectively securing the device within the area of interest. As with right anchors **24**, left anchors **26** are of sufficient length to securely engage tissue within and/or adjacent to the septal defect to be treated. For example, when treating a patent foramen ovale, left anchors **26** preferably engage tissue within and/or adjacent to the left-atrial opening patent foramen ovale. In a preferred embodiment, right anchor **24** and left anchor **26** are covered with tantalum coil **28**, or other radiopaque material, to allow for visualization of the position and location of embolic filtering device **10** after implantation in a subject. First base **16** and second base **18** and, for that matter, any portion of device **10** can likewise be comprised of radiopaque materials to provide even more visual points of reference in the imagery of embolic filtering device **10**.

[0038] In another embodiment illustrated in FIG. 3, provided is a frame **12** having first base **16**, but without second base **18**, and shortened arms **20** and **22**. By eliminating second base **18**, the amount of hardware implanted in the passage to be treated is minimized. Since, as discussed below, second base **18** resides closest to the left atrium of the heart when embolic filtering device **10** is used to treat a patent foramen ovale, eliminating second base **18** minimizes the amount of hardware adjacent to or within the left atrium, decreasing the chance the operation of the left atrium will be comprised, and reducing the surface area upon which blood clots can form.

[0039] Embolic filter **14** is removably coupled to frame **12**, and is preferably comprised of plurality of braided wire strands having a predetermined relative orientation and interstitial space between the strands. Those skilled in the art will appreciate that the number and diameter of the wires used may be varied to achieve the desired density and stiffness of the fabric, and the known size of the emboli sought to be filtered. In a preferred embodiment, the wire mesh consists of at least 96 strands of 0.002" diameter wire, situated at an angle of approximate 35° relative to the longitudinal axis **24**. Suitable wire strand materials may be selected from a group consisting of a cobalt-based low thermal expansion alloy referred to in the field as "Elgiloy," nickel-based high temperature high-strength "superalloys" (including nitinol), nickel-based treatable alloys, a number of different grades of stainless steel, and polymers, including polyester, nylon, polytetrafluoroethylene (PTFE), polyurethane, polyaryletheretherketone (PEEK), and polyglycolic acid (PGA), polylactide (PLA), polyepsilon-caprolactone, polyethylacrylate (PEA). Platinum and alloys of platinum can also be co-braided, co-knitted or co-woven into mesh **14** to assist in determining where mesh is positioned within the patent foramen ovale. In a preferred embodiment, the wire strands are made from a shape memory alloy, NiTi (known as nitinol) which is an approximately stoichiometric alloy of nickel and titanium and may also include minor amounts of

other metals to achieve desired properties. The frame **12** of device **10**, and its components, including base **16**, base **18**, right arms **24** and left arms **26**, are also preferably manufactured from so-called shape memory alloys. Such alloys tend to have a temperature induced phase change which will cause the material to have a preferred configuration which can be fixed by heating the material above a certain transition temperature to induce a phase change in the material. When the alloy is cooled, the alloy will "remember" the shape it was in during the heat treatment and will tend to assume that configuration, unless constrained from doing so.

[0040] Handling requirements and variations of NiTi alloy compositions are known in the art. For example, U.S. Pat. No. 5,067,489 (Lind) and U.S. Pat. No. 4,991,602 (Amplatz et al.), the entire teachings of which are herein incorporated by reference, discuss the use of shape memory NiTi alloys in guide wires. Such NiTi alloys are preferred, at least in part, because they are commercially available and more is known about handling such alloys than other known shape memory alloys. NiTi alloys are also very elastic and are said to be "superelastic" or "pseudoelastic." This elasticity allows device **10** to return to a preset configuration after deployment from a catheter or other delivery device. The relaxed configuration is generally defined by the shape of the fabric when it is deformed to generally conform to the molding surface of the mold in which it was created. The wire stands are manufactured by standard braiding processes and equipment.

[0041] Embolic filter **14** of the present invention is preferably in the shape of a three-dimensional ball or sphere, as exemplified in FIGS. 2A and 2C. Starting with a tubular piece of braided mesh or the like, the three-dimensional ball or sphere, as exemplified in FIG. 2A, is, for example, made by swaging a first end of the mesh with a first fastener **30**, and pushing said first fastener **30** upwards into the lumen of the tubular mesh, to create interior lobes **29**. A center portion of the mesh is then swaged with a second fastener **32**, creating an interior embolic filter portion **34**. The remaining mesh is then extended back over said first fastener **30** and interior embolic filter portion **34**, and the second end of the braided tubular mesh is swaged with a third fastener **36**. First fastener **30**, second fastener **32**, and interior embolic filter portion **34** are in effect situated within exterior embolic filter portion **38**. Third fastener **36** is situated outside of said exterior embolic portion **38**. In a preferred embodiment, fasteners **30**, **32** and **36** are collars having a central lumen. The lumens of the collars are substantially aligned along a common longitudinal axis **25**, and dimensioned to receive a guide wire **40**. Embolic filter **14** is preferably secured to frame **12** by inserting third fastener **36** into the lumen of first base **16** of frame **12**. To reduce the chance of third fastener **36** from disengaging from first base **16**, third fastener **36** and first base **16** can be coupled together, either by a mechanical locking means such as that created by a press fit, a melted polymer interlock, or hot melt adhesive, or by plasma welding. Plasma welding is the preferred coupling method, as it allows first base **16** to be shorter, since no portal is required on the base. When coupled to frame **12**, embolic filter **14** resides at least partially between arms **20** and **22**, such that the lumens of fasteners **30**, **32**, and **36** are substantially aligned with the lumens of first base **16** and second base **18** (if employing a frame with second base **18**), along longitudinal axis **24**. A plug composed of collagen, fabric, an adhesive, polymer or foam, for example, may be disposed