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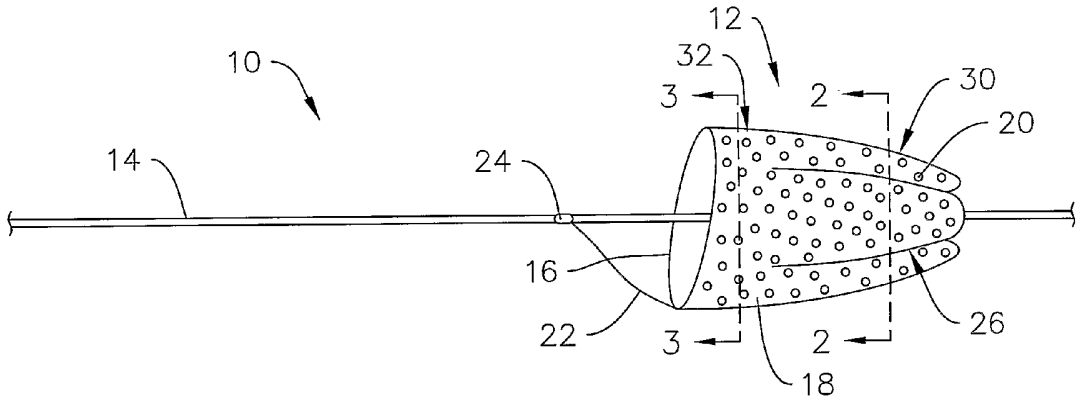
(54) Title: FILTER MEMBRANE WITH INCREASED SURFACE AREA



(57) Abstract: A filtering device with an increased surface area, and method of making and using the same. The present invention comprises a filtering device including an elongate shaft and a filter coupled to the shaft. The filter may include a filter membrane configured to have an increased surface area.

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FILTER MEMBRANE WITH INCREASED SURFACE AREA

Field of the Invention

The present invention pertains to filtering devices. More particularly, the present invention pertains to embolic protection filtering devices having a filter membrane with an increased surface area.

Background

Heart and vascular disease are major problems in the United States and throughout the world. Conditions such as atherosclerosis result in blood vessels becoming blocked or narrowed. This blockage can result in lack of oxygenation of the heart, which has significant consequences since the heart muscle must be well oxygenated in order to maintain its blood pumping action.

Occluded, stenotic, or narrowed blood vessels may be treated with a number of relatively non-invasive medical procedures including percutaneous transluminal angioplasty (PTA), percutaneous transluminal coronary angioplasty (PTCA), and atherectomy. Angioplasty techniques typically involve the use of a balloon catheter. The balloon catheter is advanced over a guidewire such that the balloon is positioned adjacent a stenotic lesion. The balloon is then inflated and the restriction of the vessel is opened. During an atherectomy procedure, the stenotic lesion may be mechanically cut away from the blood vessel wall using an atherectomy catheter.

During angioplasty and atherectomy procedures, embolic debris can be separated from the wall of the blood vessel. If this debris enters the circulatory system, it could block other vascular regions including the neural and pulmonary vasculature. During angioplasty procedures, stenotic debris may also break loose due to manipulation of the blood vessel. Because of this debris, a number of devices, termed embolic protection devices, have been developed to filter out this debris.

Brief Summary

The invention provides design, material, manufacturing method, and use alternatives for intravascular filtering devices. In at least some embodiments, these filtering devices include a shaft having an embolic protection filter coupled thereto. The filter may adapted and configured to have an increased surface area or otherwise include other improvements. These and other desirable features are described in greater detail below.

Brief Description of the Drawings

Figure 1 is side view of an example embolic protection filtering device;

Figure 2 is a cross-sectional view of the filtering device through line 2—2;

Figure 3 is a cross-sectional view of the filtering device through line 3—3;

Figure 4 is side view of another example embolic protection filtering device;

Figure 5 is a cross-sectional view of the filtering device through line 5—5;

Figure 6 is a cross-sectional view of the filtering device through line 6—6;

Figure 7 is a cross-sectional view of the filtering device through line 7—7;

Figure 8 is a side view of another example embolic protection filtering device;

Figure 9 is a side view of a portion of the filtering device shown in Figure 8;

Figure 10 is a side view of another example embolic protection filtering device;

Figure 11 is a side view of another configuration of the filtering device shown in Figure 10 ; and

Figure 12 is a side view of another example embolic protection filtering device.

Detailed Description

The following description should be read with reference to the drawings wherein like reference numerals indicate like elements throughout the several views. The detailed description and drawings illustrate example embodiments of the claimed invention.

For a number of reasons, it may be desirable to augment the amount of surface area on a device that can be used for filtering debris. Figure 1 is a side view of an example filtering device 10 including a filter 12 having an augmented surface area. This structural feature may improve the functioning of filter 12, for example, by increasing the amount of debris filter 12 can hold, by contributing to more efficient flow through filter 12, and by enhancing the strength of filter 12. It can be appreciated that the desirable structural features of filter 12 may also be described in other ways (as an alternative or in addition to having an augmented surface area) such as having an augmented filtering capability, filtering ability, filtering capacity, and the like. The augmented surface area may also provide filter 12 (and/or filtering device 10) with a number of additional desirable features including those described below.

In general, filter 12 may be adapted to operate between a first generally collapsed configuration and a second generally expanded configuration for collecting

debris in a body lumen. In some embodiments, filter 12 and/or filtering device 10 can be delivered to an appropriate intravascular location, for example "downstream" of an intravascular lesion, using an appropriate filter delivery device. Similarly, filter 12 can be removed from the vasculature at the desired time by an appropriate filter retrieval device.

Filter 12 may be coupled to a shaft 14 and may include a filter frame 16 and a filter membrane or fabric 18 coupled to filter frame 16. Frame 16 may take the form of any one of a number of appropriate shapes and configurations. For example, frame 16 may comprise a generally circular filter mouth or loop, which may define the primary opening for blood to travel into and be filtered by filter 12. However, essentially any appropriate shape or configuration may be utilized without departing from the spirit of the invention.

Frame 16 may be comprised of any appropriate material. For example, frame 16 may be comprised of a "self-expanding" shape-memory material such as nickel-titanium alloy that may be configured to bias filter 12 to be in the second expanded configuration. Alternatively, frame 16 may be comprised of essentially any appropriate metal, metal-alloy, polymer, combinations thereof, and the like including any of the materials described herein. In some embodiments, frame 16 or portions thereof may be doped with, plated with, or otherwise include a radiopaque material. Radiopaque materials are understood to be materials capable of producing a relatively bright image on a fluoroscopy screen or another imaging technique during a medical procedure. This relatively bright image aids the user of device 10 in determining its location. Some examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, plastic material loaded with a radiopaque filler, and the like. For example, a radiopaque wire disposed about a portion of frame 16.

Filter membrane 18 may be comprised of any appropriate material such as a polymer and may be drilled (for example, formed by known laser techniques) or otherwise include one or more openings 20. Holes or openings 20 can be sized to allow blood flow therethrough but restrict flow of debris or emboli floating in the body lumen or cavity. In at least some embodiments, filter membrane 18 may be configured to augment the surface area of filter 12 as is described in more detail below.

One or more struts 22 may extend between frame 16 and shaft 14. In some embodiments, struts 22 can be coupled to shaft 14 by a coupling 24, for example a heat-shrink tube, a crimp fitting, and the like. Alternatively, struts 22 may be coupled to shaft 14 by one or more windings of struts 22 about shaft 14. In some embodiments, struts 22 may comprise an extension or integral part of frame 16. Alternatively, struts 22 and frame 16 may comprise two distinct structures that can be attached to one another.

Shaft 14 can be made of any suitable materials including metals, metal alloys, polymers, or the like, or combinations or mixtures thereof. Some examples of suitable metals and metal alloys include stainless steel, such as 304v stainless steel; nickel-titanium alloy, such as nitinol, nickel-chromium alloy, nickel-chromium-iron alloy, cobalt alloy, or the like; or other suitable material. Although the embodiment shown in Figure 1 illustrates shaft 14 as being a guidewire, shaft 14 is not intended to be limited to being only a guidewire. It can be appreciated that shaft 14 may comprise number of different structures including a catheter (e.g., therapeutic, diagnostic, or guide catheter), endoscopic device, laproscopic device, an embolic protection device, or any other suitable device. In some embodiments, shaft 14 may comprise a tubular filter cartridge. According to this embodiment, filtering device 10 (and/or shaft 14) can be configured to be slidable over a guidewire or other suitable medical device.

As stated above, filter membrane 18 may be adapted and configured to augment the surface area of filter 12. Augmenting the surface area of filter 12 may be accomplished in a number of ways. For example, filter membrane 18 may include one or more folds or pleats 26 that increase the surface area where debris may be captured or filtered. The amount of surface area that may be added to filter 12 may depend on the "depth" or amount of folding included with each pleat 26. Accordingly, the "deeper" the amount of folding included with each pleat 26, the greater the increasing in surface area. It can be appreciated that alterations to the amount of folding or depth of pleats 26 may vary without departing from the spirit of the invention.

In at least some embodiments, pleats 26 may be defined by inward deflections of filter membrane 18. This configuration may allow filter membrane 18 to expand outwardly toward a bulbous shape when greater amounts of debris are captured. Alternatively, pleats 26 may be defined by one or more longitudinal bonds 28

between filter membrane 18 and shaft 14 as best seen in Figure 2. Bonds 28, for example, may be disposed adjacent a distal region 30 of filter 12. Portions of filter membrane 18, however, may not be bonded to shaft 14 as best seen in Figure 3. The non-bonded portion may be disposed adjacent a proximal region 32 of filter 12. Although the combination of Figures 1, 2 and 3 illustrate one example configuration of filter membrane 18 where bonds 28 are disposed along distal region 30 of filter 12 but not along proximal region 32, this arrangement is not intended to be limiting. Generally, bonds 28 may be disposed along distal region 30, along proximal region 32, along the entire length of filter 12, or any other suitable combination or arrangement. Figures 2 and 3 also illustrate more clearly that shaft 14 may comprise a tubular filter cartridge that may be slidable over a medical device such as a guidewire 34.

Figure 4 is another example filtering device 110 that is essentially the same in form and function as device 10, except that filter 112 include one or more longitudinal fibers 136 (best seen in Figures 5, 6, and 7) and that the folds or pleats 126 of filter membrane 118 may be defined by bonds 128 (best seen in Figure 5, 6, and 7) between filter membrane 118 and fibers 136. According to this embodiment, fibers 136 may act as a substrate or bonding surface for filter membrane 118 as well as help define a configuration of filter 112 that has increased surface area. Fibers 136 may also provide filter 112 with other desirable features such as strength, radiopacity, etc.

In at least some embodiments, fibers 136 may be attached to and extend distally from filter frame 116. For example, opposite ends of fibers 136 may be attached to filter frame 116 and shaft 14. According to this embodiment, the spacing between fibers 136 and shaft 14 gets larger at more proximal filter locations. For example, Figure 5 is a cross-sectional view of filter 112 at a relatively distal position, illustrating fibers 136 disposed adjacent shaft 14. Figures 6 and 7, which illustrate increasingly more proximal positions along filter 112, depict increasing radial spacing of fibers 136 from shaft 12.

Figure 8 is another example filtering device 210 that is essentially the same in form and function as any of the others described herein except that filter 212 includes one or more sinusoidal ribs 238. In at least some embodiments, sinusoidal ribs 238 may be attached to or disposed adjacent to filter frame 16 and/or filter membrane 18, and may extend distally along filter 212. The precise location and length of ribs 238, however, may vary. In general, ribs 238 may be configured for being disposed along

the region of filter 212 that contacts or may contact the interior wall of a blood vessel 240 as shown in Figure 9. This feature may be desirable, for example, because it allows a smaller portion of filter membrane 218 to be "blocked" by contact with blood vessel 240. Accordingly, the surface area of filter 212 that can be used to collect debris is increased.

Another example filtering device 310 is shown in Figure 10. Device 310 is essentially the same in form and function as any of the other devices described herein except that filter 310 includes a distal apex ring member 342 that is slidable along shaft 14. Accordingly, filter 312 may be able to shift from a first relatively shortened or inverted configuration (as shown in Figure 10) to a second relatively elongated or everted configuration (as shown in Figure 11).

Shifting between the first and second configurations may be accomplished in a number of ways. For example, filter 312 may be originally placed within a body lumen in the first configuration and then shift to the second configuration as filter 312 becomes filled with debris. According to this embodiment, ring member 342 may frictionally engage shaft 14. However, when filter 312 becomes sufficiently full, forces exerted on filter 312 (e.g., due to fluid flow within the body lumen) may overcome the frictional force and shift filter 312 to the second configuration.

Alternatively, shifting the configuration of filter 312 may be accomplished in another example filtering device 410 by using a shifting member or rod 444 as shown in Figure 12. According to this embodiment, rod 444 may be attached to ring member 342 and extend proximally therefrom. A clinician may then grasp rod 444 and alter the configuration of filter 312 by proximally or distally shifting rod 444.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

Claims

What is claimed is:

1. An embolic protection filtering device, comprising:

an elongate shaft having a proximal end and a distal end;

a filter coupled to the shaft, the filter including a filter frame, and a filter membrane coupled to the filter frame; and

the filter membrane including one or more pleats.

2. The filtering device of claim 1, wherein the shaft comprises a guidewire.

3. The filtering device of claim 1, wherein the shaft comprises a tubular filter cartridge configured to be slidable over a guidewire.

4. The filtering device of claim 1, wherein the filter includes a proximal region and a distal region, and wherein the pleats are disposed at the distal region.

5. The filtering device of claim 1, wherein the pleats are defined by inward deflections of the filter membrane.

6. The filtering device of claim 5, wherein the pleats are defined by one or more bonds between the filter membrane and the shaft.

7. The filtering device of claim 1, further comprising one or more support fibers extending from the filter frame to a distal end of the filter.

8. The filtering device of claim 7, wherein the pleats are defined by one or more bonds between the filter membrane and the support fibers.

9. A medical device, comprising:

an elongate shaft having a proximal region and a distal region;

a filter coupled to the shaft adjacent the distal region;

the filter including a filter hoop, one or more struts extending between the filter hoop and the shaft, and a filter membrane coupled to the filter hoop and extending distally therefrom; and

the filter membrane including a proximal region and a pleated distal region, the pleated distal region being configured to augment the surface area of the filter.

10. The medical device of claim 9, wherein the shaft is a guidewire.

11. The medical device of claim 9, wherein the shaft comprises a tube configured to be slidably disposed over a guidewire.

12. The medical device of claim 9, further comprising one or more support fibers extending from the filter hoop to a distal apex of the filter.

13. The medical device of claim 12, wherein the filter membrane is coupled to the support fibers.

14. An embolic protection filtering device, comprising:

an elongate shaft;

a filter coupled to the shaft; and

means for increasing the surface area of the filter.

15. The embolic protection filtering device of claim 12, wherein the filter includes a filter membrane, and wherein means for increasing the surface area of the filter includes one or more pleats within a filter membrane.

16. The embolic protection filtering device of claim 12, wherein the filter includes one or more sinusoidal ribs disposed adjacent the filter, and wherein means for increasing the surface area of the filter includes the one or more sinusoidal ribs.

17. An embolic protection filtering device, comprising:

an elongate shaft;

a filter coupled to the shaft; and

means for augmenting the filtering capability of the filter.

18. The embolic protection filtering device of claim 17, wherein the filter includes a filter membrane, and wherein means for augmenting the filtering capability of the filter includes one or more pleats within a filter membrane.

19. The embolic protection filtering device of claim 17, wherein the filter includes one or more sinusoidal ribs disposed adjacent the filter, and wherein means for augmenting the filtering capability of the filter includes the one or more sinusoidal ribs.

20. The embolic protection filtering device of claim 17, wherein the filter includes a slidable distal apex that is slidable along the shaft, an wherein means for augmenting the filtering capability of the filter includes the slidable distal end.

21. An embolic protection filtering device, comprising:

a shaft; and

a filter coupled the shaft, the filter including a filter hoop, one or more struts extending between the filter hoop and the shaft, a filter membrane coupled to the filter hoop and extending distally therefrom, and one or more sinusoidal ribs disposed adjacent the filter material.

22. An embolic protection filtering device, comprising:

a shaft;

a filter coupled to the shaft, the filter including a filter loop, one or more struts extending between the filter loop and the shaft, and a filter membrane coupled to the filter loop;

a slidable ring member disposed at a distal apex of the filter, the ring member configured shift between a proximal first position and a distal second position.

23. The filtering device of claim 22, further comprising a shifting rod coupled to the ring member and extending proximally therefrom.

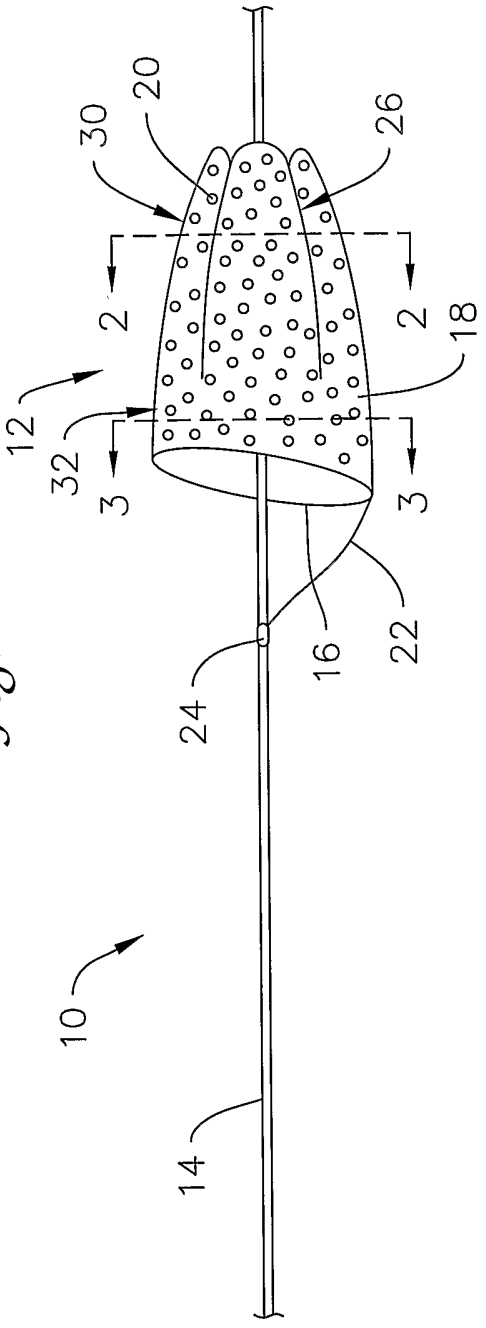

Fig.1

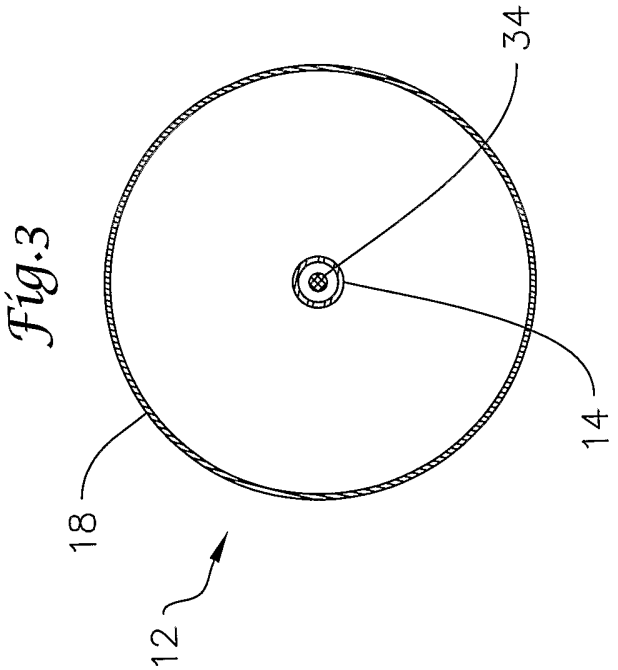

Fig.3

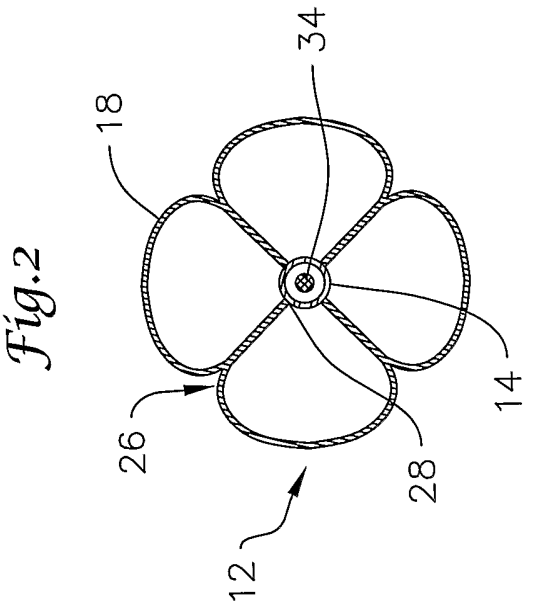

Fig.2

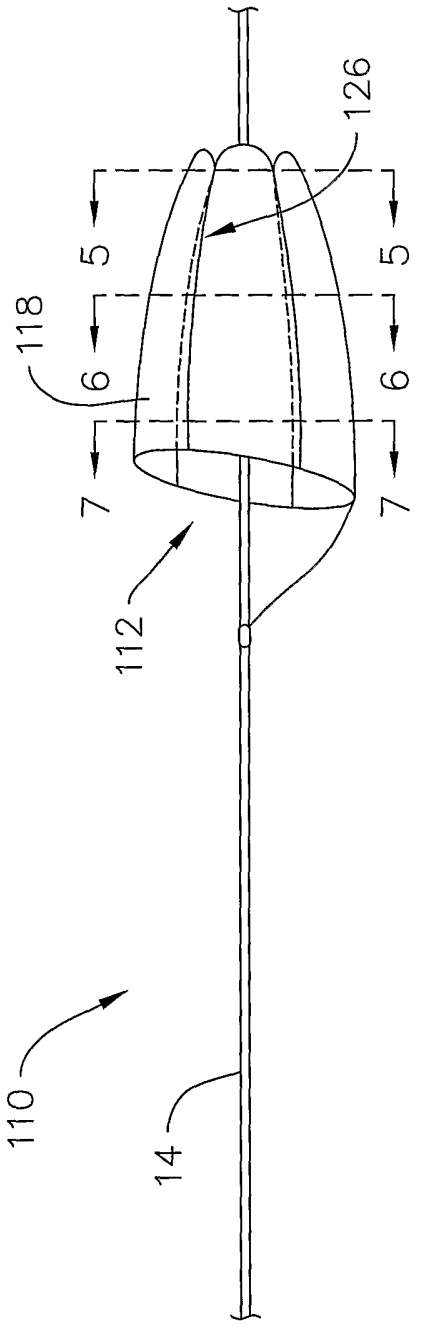

Fig.4

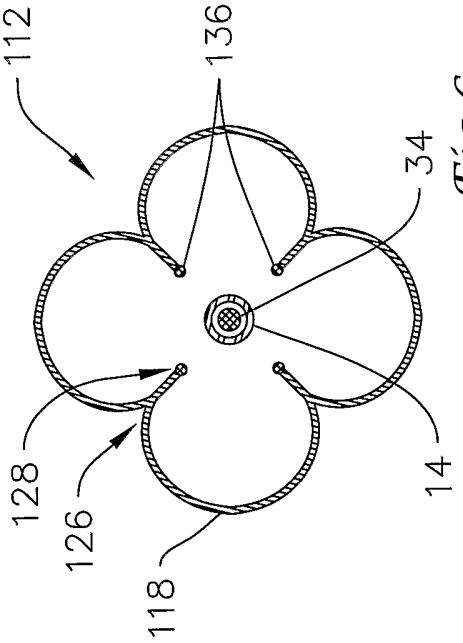

Fig.6

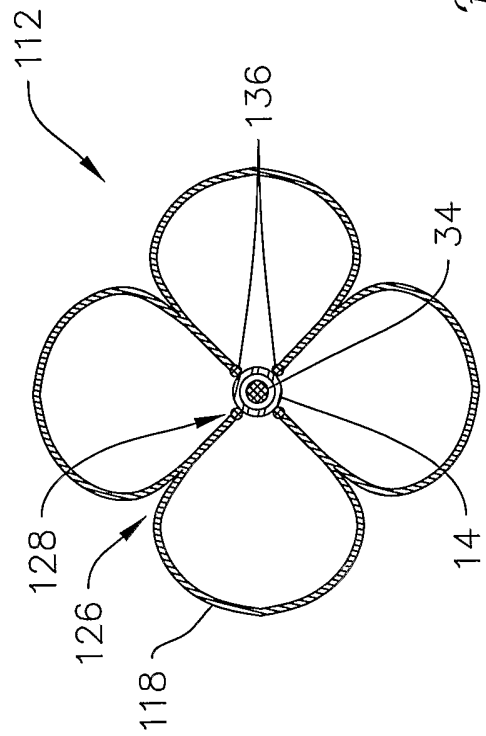

Fig.5

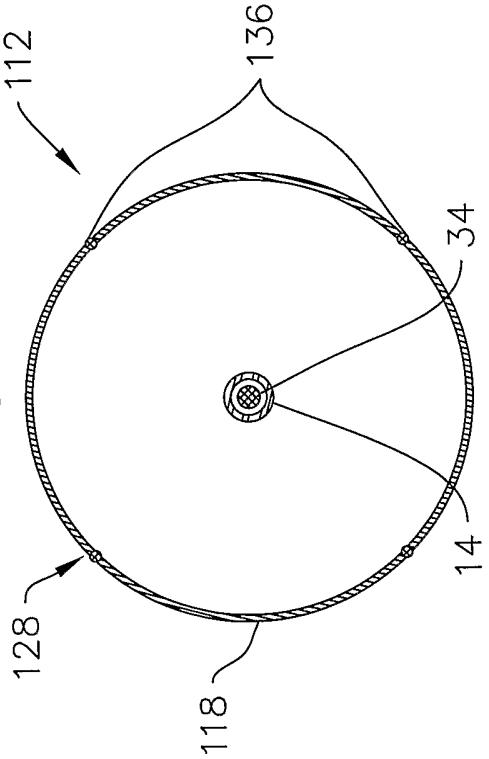

Fig.7

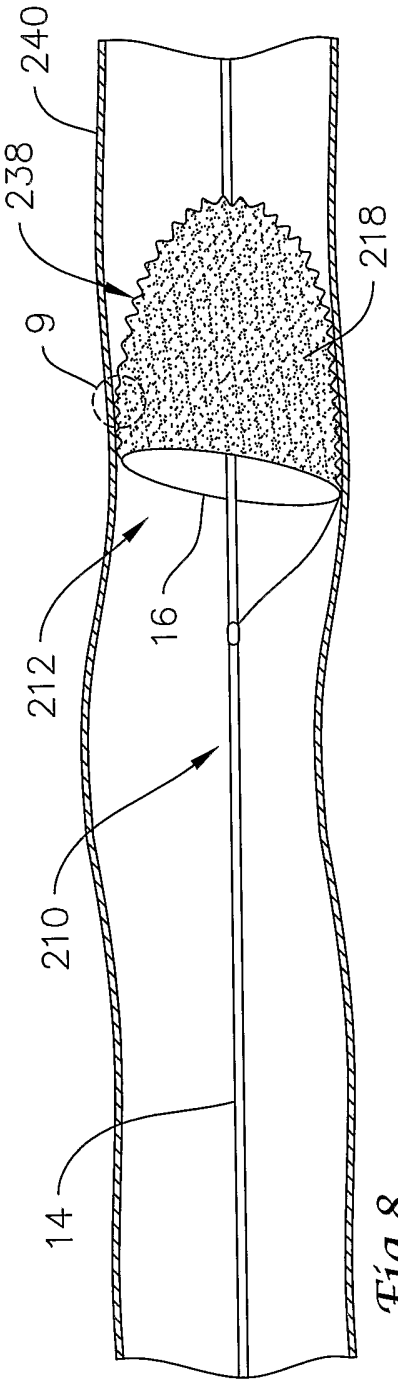

Fig.8

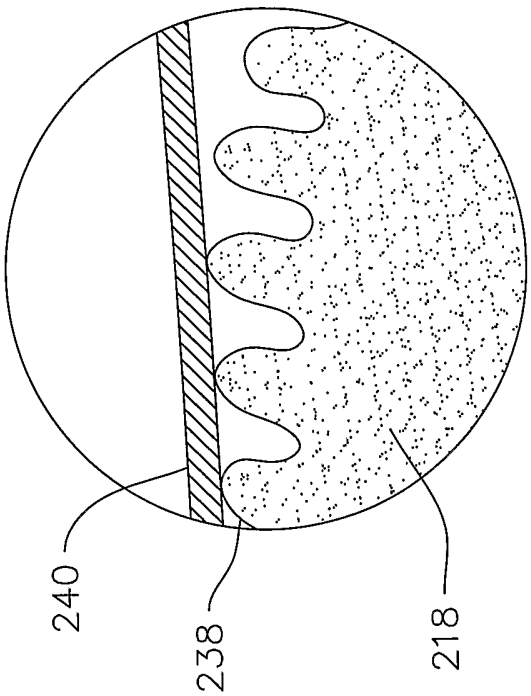

Fig.9

Fig.10

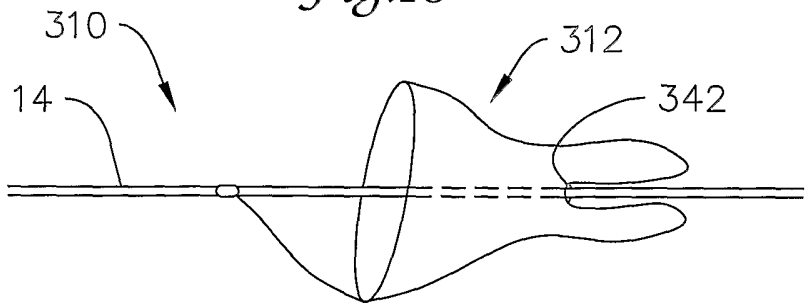

Fig.11

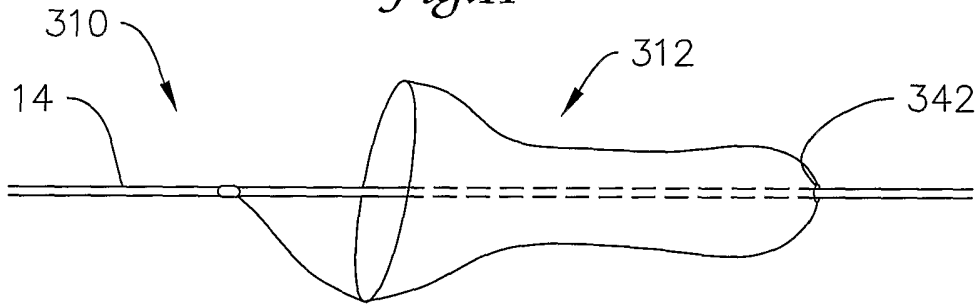

Fig.12