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CA 2946470 A1 2006/11/23

(21) 2 946 470

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(22) **Date de dépôt/Filing Date:** 2006/05/09

(41) **Mise à la disp. pub./Open to Public Insp.:** 2006/11/23

(62) **Demande originale/Original Application:** 2 607 580

(30) **Priorité/Priority:** 2005/05/12 (US60/680,601)

(51) **Cl.Int./Int.Cl.** ***A61F 2/01*** (2006.01)

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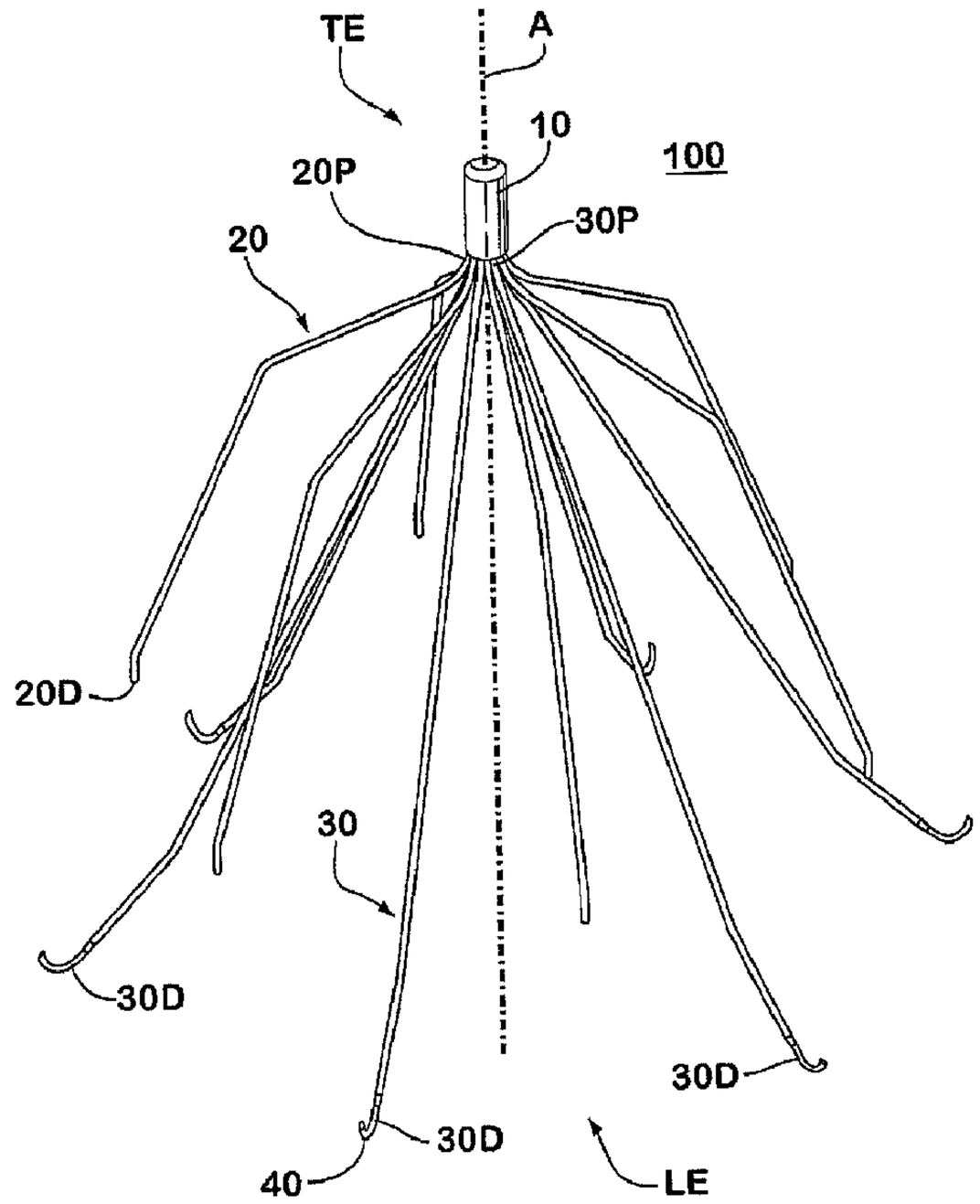
(54) **Titre : FILTRE AMOVIBLE POUR CAILLOT SANGUIN OU EMBOLE**
(54) **Title: REMOVABLE EMBOLUS BLOOD CLOT FILTER**



(57) **Abrégé/Abstract:**
A removable blood clot filter includes a number of locator members and anchor members disposed radially and extending angularly downward from a hub. The locator members include a number of linear portions having distinct axes configured to place a tip

CA 2946470 A1 2006/11/23

(21) 2 946 470

(13) A1

(57) **Abrégé(suite)/Abstract(continued):**
portion approximately parallel to the walls of a blood vessel when implanted and to apply sufficient force to the vessel walls to position the filter near the vessel centerline. The anchor members each include a hook configured to penetrate the vessel wall to prevent longitudinal movement due to blood flow. The hooks may have a cross section sized to allow for a larger radius of curvature under strain so that the filter can be removed without damaging the vessel wall.

Abstract

A removable blood clot filter includes a number of locator members and anchor members disposed radially and extending angularly downward from a hub. The locator members include a number of linear portions having distinct axes configured to place a tip portion approximately parallel to the walls of a blood vessel when implanted and to apply sufficient force to the vessel walls to position the filter near the vessel centerline. The anchor members each include a hook configured to penetrate the vessel wall to prevent longitudinal movement due to blood flow. The hooks may have a cross section sized to allow for a larger radius of curvature under strain so that the filter can be removed without damaging the vessel wall.

Title: REMOVABLE EMBOLUS BLOOD CLOT FILTER

Field of the Invention

[0001] This invention relates to a filter device that can be placed in a blood vessel to reduce the risk of embolisms and, if needed, removed from the blood vessel without causing traumatic damage to the blood vessel.

Background of the Invention

[0002] In recent years, a number of medical devices have been designed which are adapted for compression into a small size to facilitate introduction into a vascular passageway and which are subsequently expandable into contact with the walls of the passageway. These devices, among others, include blood clot filters which expand and are held in position by engagement with the inner wall of a vein, such as the vena cava. These vena cava filters are designed to remain in place permanently. Such filters include structure to anchor the filter in place within the vena cava, such as elongate diverging anchor members with hooked ends that penetrate the vessel wall and positively prevent migration in either direction longitudinally of the vessel. The hooks on filters of this type are rigid and will not bend, and within two to six weeks after a filter of this type has been implanted, the endothelium layer grows over the diverging anchor members and positively locks the hooks in place. Now any attempt to remove the filter results in a risk of injury to or rupture of the vena cava.

[0003] A number of conditions and medical procedures subject the patient to a short term risk of pulmonary embolism which can be alleviated by a filter implant. In such cases, patients are often averse to receiving a permanent implant, for the risk of pulmonary

embolism may disappear after a period of several weeks or months. However, most existing filters are not easily or safely removable after they have remained in place for more than two weeks, and consequently longer-term temporary filters that do not result in the likelihood of injury to the vessel wall upon removal are not available.

[0004] In an attempt to provide a removable filter, two filter baskets have been formed along a central shaft that are conical in configuration, with each basket being formed by spaced struts radiating outwardly from a central hub for the basket. The central hubs are held apart by a compression unit, and the locator members of the two baskets overlap so that the baskets face one another. Filters of this type require the use of two removal devices inserted at each end of the filter to draw the baskets apart and fracture the compression unit. The end sections of the locator members are formed to lie in substantially parallel relationship to the vessel wall and the tips are inclined inwardly to preclude vessel wall penetration. If a device of this type is withdrawn before the endothelium layer grows over the locator members, vessel wall damage is minimized. However, after growth of the endothelium layer the combined inward and longitudinal movement of the filter sections as they are drawn apart can tear this layer.

Summary of the Invention

[0005] The various embodiments provide for a removable blood filter that allows for filtering of an embolus in a blood vessel by utilizing a plurality of locators and a plurality of anchors. In one aspect, a filter to be placed in a flow of blood through a vessel includes a hub, at least one anchor, and at least one locator. The hub can be disposed along a longitudinal axis. The at least one anchor projects from the hub and includes a hook that penetrates a wall of the blood vessel when the filter is placed in the blood vessel. The hook can be spaced along the longitudinal axis from the hub and spaced a first radial distance from longitudinal axis. The at least one locator has a tip or portion of the locator that engages the wall of the vessel. The tip can be spaced along the longitudinal axis from the hub and spaced a second radial distance from the longitudinal axis. The second radial distance can be less than the first radial distance. The at least one

locator has at least four portions and each of the portions can be disposed on respective distinct axes.

[0006] In yet another aspect, the various embodiments also provides for a filter to be placed in a flow of blood through a vessel. The filter includes a hub, at least one anchor, and at least one locator. The hub can be disposed along a longitudinal axis. The at least one anchor projects from the hub and includes a hook that penetrates a wall of the blood vessel when the filter is placed in the blood vessel. The hook can be spaced along the longitudinal axis from the hub and spaced a first radial distance from the longitudinal axis. The at least one locator projects from the hub and has a tip or portion of the locator that engages the wall of the vessel. The tip can be spaced along the longitudinal axis from the hub and spaced a second radial distance from the longitudinal axis where the second radial distance can be less than the first radial distance. The locator can be disposed proximate the hub and has at least four portions, and each of the at least four portions can be disposed on respective distinct axes. The at least four portions can include a curved portion being disposed on a radius of curvature that extends along the longitudinal axis.

[0007] In yet a further aspect of the various embodiments, a filter is provided to be placed in a flow of blood through a vessel. The filter includes a hub, at least one anchor and at least one locator. The hub can be disposed along a longitudinal axis. The at least one anchor projects from the hub and includes a hook that penetrates a wall of the blood vessel when the filter is placed in the blood vessel, spaced along the longitudinal axis from the hub, and spaced a first radial distance from longitudinal axis. The at least one locator projects from the hub and has a tip or portion of the locator that engages the wall of the vessel. The tip can be spaced along the longitudinal axis from the hub, and spaced a second radial distance from the longitudinal axis, where the second radial distance can be less than the first radial distance. The locator has a first portion distal to the hub and a second portion proximal to the hub. Each of the first and second portions can be generally linear and disposed on distinct axes oblique with respect to the longitudinal

axis, where the length of the first portion can be greater than a length of the second portion.

[0008] In yet an additional aspect of the various embodiments, a filter is provided to be placed in a flow of blood through a vessel. The filter includes a hub, at least one anchor and at least one locator. The hub can be disposed along a longitudinal axis. The at least one anchor projects from the hub and includes a hook that penetrates a wall of the blood vessel, spaced along the longitudinal axis from the hub, and spaced a first radial distance from the longitudinal axis. The at least one locator projects from the hub and has a tip or portion of the locator that engages the wall of the vessel. The tip can be spaced along the longitudinal axis from the hub, and spaced a second radial distance from the longitudinal axis, where the second radial distance can be less than the first radial distance. The locator has first and second portions oblique to the longitudinal axis. The first portion can be distal to the hub, and a second portion can be proximal to the hub, where a length of the first portion being greater than a length of the second portion.

[0009] In yet another aspect of the various embodiments, a filter is provided to be placed in a blood vessel that includes a blood vessel wall. The filter includes a hub, and a first and a second set of members. The hub can be disposed along a longitudinal axis. Each of the first set of members extends from the hub. Each of the first set of members includes a hook spaced along the longitudinal axis from the hub, each hook being spaced radially from the longitudinal axis a first distance. Each of the second set of members extends from the hub and includes a tip being spaced along the longitudinal axis from the hub. Each tip can be spaced radially from the longitudinal axis a second distance less than the first distance.

[0010] In yet a further aspect of the various embodiments, a filter to be placed in a blood vessel is provided. The filter includes a hub, a plurality of anchors and a plurality of locators. The hub can be disposed along a longitudinal axis. The plurality of anchors branches from the hub. Each anchor includes a hook that: (i) penetrates a wall of the blood vessel, (ii) can be spaced along the longitudinal axis from the hub, and (iii) can be

radially spaced from the longitudinal axis a first distance. The plurality of locators branches from the hub. Each locator includes a base portion proximate the hub, a first portion that extends from the base portion and along a first axis, a second portion that extends from the first portion and along a second axis, which can be distinct from the first axis, and a tip portion that extends from the second portion and along a tip axis, which can be distinct from the first and second axes. The tip portion (i) engages the wall of the blood vessel, (ii) can be spaced along the longitudinal axis from the hub, and (iii) can be radially spaced from the longitudinal axis a second distance, which can be less than the first radial distance.

[0011] In yet a further aspect of the various embodiments, a filter to be placed in a blood vessel is provided. The filter includes a hub, a plurality of anchors and a plurality of locators. The hub can be disposed along a longitudinal axis. The plurality of anchors branches from the hub. Each anchor includes a hook that: (i) penetrates a wall of the blood vessel, (ii) can be spaced along the longitudinal axis from the hub, and (iii) can be radially spaced from the longitudinal axis a first distance. The plurality of locators branches from the hub. Each locator includes a base portion proximate the hub, a tip portion that (i) can engage the wall of the blood vessel, (ii) can be spaced along the longitudinal axis from the hub, and (iii) can be radially spaced from the longitudinal axis a second distance, which can be less than the first radial distance, and an intermediate portion coupling the base and tip portion. The intermediate portion can include a first linear segment extending from the base portion a first length along a first axis, which can be oblique with respect to the longitudinal axis and a second linear segment extending between the tip portion and first portions a second length, which can be greater than the first length, and along a second axis, which can be oblique respect to the longitudinal axis and can be distinct from the first axis.

[0012] In yet another aspect of the various embodiments, a filter is provided. The filter is to be placed in a flow of blood contained by a wall of a blood vessel. The filter includes a hub that extends along a longitudinal axis and at least one first member having first and

second generally linear segments. The filter also includes at least one second member having third and fourth generally linear segments. The first segment defines a portion of a first cone when the first segment is rotated about the longitudinal axis. The second segment defines a cylinder when the second segment is rotated about the longitudinal axis. The third and fourth segments define respective portions of a third and fourth cones when each of the segments is rotated about the longitudinal axis. At least one of the third and fourth segments has a hook portion that penetrates the wall of a blood vessel.

[0013] In yet a further aspect of the various embodiments, a blood filter is provided to be placed in a flow of blood contained by a wall of a blood vessel. The filter includes a hub, at least one anchor and a plurality of locators. The hub can be disposed along a longitudinal axis extending generally parallel to the flow of blood. The at least one anchor includes a hook that penetrates the wall of the vessel. The at least one anchor defines a generator of a first conical shape about a longitudinal axis. The first conical shape includes: (i) an apex disposed proximate the hub, each anchor (ii) can be spaced along the longitudinal axis from the hub, and (iii) can be radially spaced from the longitudinal axis at a first distance. The plurality of locators branches from the hub and defines a first frustum having a geometric centroid along the longitudinal axis.

[0014] In yet another aspect, a filter is provided. The filter can be placed in a flow of blood contained by a wall of a blood vessel. The filter includes a hub, a plurality of anchors, and a plurality of locators. The hub can be disposed along a longitudinal axis. The plurality of anchors branches from the hub. Each anchor can include a hook that (i) penetrates a wall of the blood vessel, (ii) can be spaced along the longitudinal axis from the hub, and (iii) can be radially spaced from the longitudinal axis a first distance. The plurality of locators branches from the hub. Each locator includes a base portion extending arcuately from the hub. The base portion has a radius of curvature about a transverse axis located at a second distance generally radially from the longitudinal axis. Each of the locators has a tip contiguous to the wall of the vessel. A portion of the tip closest to the hub can be spaced at a third distance along the longitudinal axis from the

hub and spaced a fourth radial distance from the longitudinal axis, the fourth radial distance being less than the third distance.

[0015] The various embodiments described above may further include a radio-opaque material on or as part of the filter hub. Also, the various embodiments described above may further include a bio-active agent incorporated with or as part of the filter.

[0016] The various embodiments further provide a method of centering a blood filtering device within a blood vessel having a plurality of locators extending from a hub to define a first volume and a plurality of anchors extending from the hub to define a second volume. The method can be achieved by enclosing more than 15 percent of the second volume in the first volume, and engaging a hook provided on each locator onto a wall of the blood vessel.

Brief Description of the Drawings

[0017] The accompanying drawings, which are incorporated herein and constitute part of this specification, illustrate presently preferred embodiments of the invention, and, together with the general description given above and the detailed description given below, serve to explain features of the invention.

[0018] Figure 1 is a top down perspective view of a preferred embodiment of the blood filter.

[0019] Figure 2 is a bottom up perspective view of the embodiment of Figure 1.

[0020] Figure 3 is a plan view of the filter of Figure 1 on longitudinal axis A.

[0021] Figure 4A is a side view of the filter viewed along view 4A-4A in Figure 3.

[0022] Figure 4B is a side view of one arm or locator member of the filter of Figure 1.

[0023] Figure 5A is a side view of the filter viewed along view 5A-5A in Figure 3.

[0024] Figure 5B is a side view of one locator member of the filter of Figure 1.

[0025] Figure 5C is a side view of an alternative locator arrangement having a retention member disposed on the locator.

[0026] Figure 5D is a side view of another locator arrangement having a support member to reduce or prevent penetration of a blood vessel wall by the locator.

[0027] Figure 6 is a close up side view of a hook of the anchor member for the filter of Figure 1.

[0028] Figure 7 is a shaded perspective view of a volume generated by the locator member outside of a hub as it rotates or sweeps around longitudinal axis A.

[0029] Figure 8 is a shaded perspective view of a volume generated by the anchor member outside the hub as the anchor member is rotated or sweeps around the longitudinal axis A.

[0030] Figure 9 illustrate the volume of the anchor member visible outside the volume of the locator member.

[0031] Figures 10-14 illustrate yet another preferred embodiment having a retrieving hook portion.

Detailed Description of the Preferred Embodiments

[0032] The various embodiments will be described in detail with reference to the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[0033] As used herein, the terms "about" or "approximately" for any numerical values or ranges indicates a suitable dimensional tolerance that allows the part or collection of components to function for its intended purpose as described herein. Also, as used herein, the terms "patient", "host" and "subject" refer to any human or animal subject and are not intended to limit the systems or methods to human use, although use of the subject invention in a human patient represents a preferred embodiment.

[0034] Figures 1-14 illustrate the preferred embodiments. Referring to Figure 1, a filter 100 is illustrated in a perspective view. The filter 100 includes a hub 10, locator member 20, and anchor member 30 that has a hook 40. The filter 100 can be made from a plurality of elongate wires, which are preferably metal, such as, for example, Elgiloy, and more preferably are a super elastic shape memory alloy, such as Nitinol. The wires are held together at the filter trailing end by a hub 10 by a suitable connection technique, such as, for example, welding, laser welding, or plasma welding or being bonded together. Preferably, the wires are plasma welded. As used herein, "wire" refers to any elongated member of narrow cross section, including rods, bars, tubes, wire and narrow sections cut from thin plate, and is not intended to limit the scope of the invention to elongated members of circular cross section, cut from wire stock or manufacture according to a particular method of metal forming.

[0035] The locator member 20 has a proximal locator end 20P and a distal locator end 20D. Similarly, the anchor member 30 has a proximal anchor end 30P and a distal anchor end 30D. The distal anchor end 30D can be provided, as shown in Figure 6, with hook 40.

[0036] Referring to Figures 4A and 4B, the locator member 30 may be provided with a plurality of locator segments, preferably between 3 and 6 segments and more preferably four locator segments LS1, LS2, LS3, LS4. First locator segment LS1 may be a curved portion extending away from the hub in a first direction along the longitudinal axis A. In an embodiment, the second locator segment LS2 extends generally linearly along a second axis 110; third locator segment LS3 extends generally linearly along a third axis 120; and the fourth locator segment LS4 extends generally linearly along a fourth axis 130. In a preferred embodiment, the various axes A, 110, 120, 130, and 140 are distinct from one another in that each may intersect with one another but none of them are substantially collinear with each other.

[0037] The locator segment LS2 may be distinct from locator segment LS3 by virtue of a joint or bend LJ1. The locator segment LS3 may be distinct from locator segment LS4

via a join or bend LJ2. The joint or bend LJ1 or LJ2 can be viewed as a location formed by the intersection of the segments defining a radiused portion connecting any two segments.

[0038] The locators 20 may range from 3 to 12 locators. The filter embodiment illustrated in Fig. 4A includes six locators that are generally equiangularly spaced about axis A. In the embodiment illustrated in Fig. 4B, locator segment LS1 extends through an arc with a radius of curvature R_1 whose center may be located along an axis orthogonal to axis A over a radially transverse distance d_3 and over a longitudinal distance L_4 as measured from a terminal surface 12 of the hub 10 along an axis generally parallel to the longitudinal axis A. The locator segment LS2 extends along axis 110 to form a first angle θ_1 with respect to the longitudinal axis A whereas the locator segment LS3 extends along axis 120 to form second angle θ_2. As shown in Figure 4B, the first locator joint or bend LJ1 may be located at a longitudinal length L1 generally parallel to axis A from the terminal surface 12. The first locator joint or bend LJ1 may be also located at a distance of about one-half distance "d_1" from axis A on a generally orthogonal axis with respect to axis A as shown in Fig. 4A, where the distance d_1 is the distance between inside facing surfaces of respective diametrically disposed locators 20. The second locator joint LJ2 may be located over a longitudinal length L_2 generally parallel to axis A. The second locator join LJ2 may be located over a distance of about one-half diameter "d_2" from axis A. The distance d_2 is the distance between the outermost surface of the fourth segment LS4 of respective diametrically disposed locators 20. The thickness of locator member 20 is t_1. Where the locator member 20 is a wire of circular cross-section, the thickness t_1 of the locator 20 may be the diameter of the wire.

[0039] A range of values may be used for the aforementioned dimensional parameters in order to provide locator members that will locate the filter within the vein or vessel in which the filter is to be applied in a manner that positions segment LS4 approximately parallel to the walls of the vein or vessel and provides sufficient lateral force against the vein or vessel wall to center the filter but not so much force as to cause injury to the wall.

For example, a filter intended to be placed in a narrow vein or vessel, such as a human infant or canine vena cava, may have smaller dimensions L1, L2, L3, L4, LS1, LS2, LS3, LS4, d1 and d2 so that the positioning members can deploy sufficiently to accomplish the positioning and filtering functions, than a filter intended to be placed in a large vein or vessel, such as an adult human vena cava or other vessel. In an example embodiment suitable for an adult human vena cava filter, when the filter is at the temperature of the subject and unconstrained, the radius of curvature R_1 is from about 0.02 inches to about 0.1 inches with the center of the radius R_1 being located over a distance d_3 from the axis A of about 0.1 inches and length L_4 of about 0.2 inches; the length L_1 is about 0.3 inches; length L_2 is about 0.9 inches; distance d_1 (as measured to the inside facing surfaces of diametrically disposed locators 20) is about 0.8 inches; distance d_2 is about 1.5 inches, the first angle θ_1 is about 58 degrees, the second angle θ_2 is about 22 degrees; and the thickness t1 of the locator is about 0.013 inches. It should be noted that the values given herein are approximate, representing a dimension within a range of suitable dimensions for the particular embodiment illustrated in the figures, and that any suitable values can be used as long as the values allow the filter to function as intended in a blood vessel of a subject.

[0040] Referring to Figures 5A and 5B, the hub 10 can be provided with an internal cylindrical opening with a diameter of about two times the distance d_8. Each of the plurality of anchor members 30 can be provided with a first anchor segment LA1, a portion of which is disposed within the hub 10, connected to a second anchor segment LA2 by a first anchor joint or bend AJ1, which can be connected to a third anchor segment LA3 via a second anchor joint or bend AJ2. The third anchor segment LA3 can be connected to the hook 40 via third anchor joint or bend AJ3. The first anchor segment LA1 extends obliquely with respect to axis A. The second anchor segment LA2 extends along axis 130 oblique with respect to the axis A over an angle θ_3 with respect to the longitudinal axis A. The third anchor segment LA3 extends along axis 140 oblique with respect to the longitudinal axis A over an angle θ_4. The second anchor joint or bend AJ2 can be located at a sixth longitudinal distance L6 as measured on an axis generally

parallel to the axis A from the terminal surface 12 of the hub 10 and at about one half the fourth distance d_4 as measured between generally diametrical end points of two anchors 30 on an axis generally orthogonal to the axis A. The third anchor joint AJ3 can be located at a seventh longitudinal distance L7 as measured along an axis generally parallel to axis A and at a transverse distance of about one-half distance d_7 as measured on an axis orthogonal to the axis A between the inner surfaces of two generally diametric anchors 30. The thickness of anchor member 30 is nominally t2. Where the anchor member 30 is a wire of circular cross-section, the thickness t2 of the anchor 30 may be the diameter of the wire. As shown in Figure 5B, the hook 40 may be contiguous to a plane located at a longitudinal distance of L10 as measured to the terminal surface 12 of hub 10. The hook 40 can be characterized by a radius of curvature R2, in its expanded configuration at a suitable temperature, e.g., room temperature or the internal temperature of a subject. The center of the hook curvature R2 can be located at a distance L_{11} as measured along an axis generally parallel to the axis A from the terminal surface 12 of hub 10 and at one-half distance d_6 as measured between two generally diametrical hooks 40. The tips 40T of respective diametric hooks 40 may be located at longitudinal distance L12 (which may be approximately the same as longitudinal distance L7 to the third anchor joint AJ3) and at one half of distance d7 between diametric hooks 40.

[0041] A range of values may be used for the aforementioned dimensional parameters in order to provide anchor members that will locate and anchor the filter within the vein or vessel in which the filter is to be applied in a manner that positions hooks 40 in contact with the walls of the vein or vessel and provides sufficient lateral force against the vein or vessel wall to ensure the hooks engage the wall but not so much force as to cause injury to the wall. For example, a filter intended to be placed in a narrow vein or vessel, such as a child or dog vena cava, may have smaller dimensions so that the anchor members can deploy sufficiently to accomplish the positioning, anchoring and filtering functions, than a filter intended to be placed in a large vein or vessels, such as an adult vena cava or other vessel. In an example embodiment suitable for an adult human vena cava filter, when the filter is at the temperature of the subject and unconstrained, the longitudinal distance L8

is about 0.02 inches; L9 is about 0.2 inches; L10 is about 1.3 inches; L11 is about 1.2 inches; d6 is about 1.5 inches; d7 is about 1.6 inches; d8 is about 0.01 inches; d9 is between 1.5 and 1.6 inches; L12 is about 1.2 inches; the radius of curvature R2 is about 0.03 inches; and the thickness t2 of the anchor member is about 0.013 inches. Most preferably, a very small radius of curvature R3 can characterize anchor joint or bend AJ2 where R3 can be about 0.01 inches.

[0042] In situation where additional retention of the filter may be desired, an anchor member can be coupled to the locator. One arrangement is shown exemplarily in Figure 5C, where a hook 22 can be coupled to the locator proximate the tip portion. In this arrangement, both the tip portion and hook 22 are configured so that the locator does not penetrate through the blood vessel wall by formation of a stop region 22a defined by both the locator tip and the hook 22. Another arrangement can be by coupling or forming a hook in the same configuration as hook 40 for the anchor members. In yet another arrangement, shown here in Figure 5D, where it may not be desirable to utilize a hook, one or more stop members 24 can be provided on the locator at any suitable locations. As shown in Figure 5D, the stop member 24 is in the form of a truncated cone coupled to the locator. However, the stop member 24 can be of any configuration as long as the member 24 reduces or prevents penetration of the locator through the blood vessel wall. And in yet a further arrangement, the hook 22 (or hook 40) can be utilized in combination with the stop member 24 such as for example, a hook 22 coupled to a first locator, a hook 40 coupled to a second locator, a stop member 24 on a third locator, a combination of hook 22 and stop member 24 on a fourth locator, a combination of hook 40 and stop member 24 on a fifth locator.

[0043] Referring to Figure 6, the hook 40 can be provided with a proximal hook portion 40P and a distal hook portion 40D on which a sharpened tip 40T is provided. The hook 40 can be formed to have a thickness t3. Where the hook 40 is formed from a wire having a generally circular cross-section, the thickness t3 may be generally equal to the outside diameter of the wire. In an embodiment, the hook thickness t3 is approximately

0.5 to approximately 0.8 that of the anchor thickness t2. The wire can be configured to follow a radius of curvature R2 whose center is located at longitudinal distance L11 and radial distance d9 when the filter is at the temperature of a subject, as discussed above. The tip 40T can be provided with a generally planar surface 40D whose length can be approximately equal to length h1. The tip 40T may be located over a distance h2 from a plane tangential to the curved portion 40S.

[0044] Referring to Figure 7, the locators 20 are illustrated has being bounded by a first compound surface of revolution SR1 about axis A by rotating one of the locators 20 about axis A for 360 degrees. The first compound surface of revolution SR1 includes a portion of a truncated hyperboloid H, first frustum F1, second frustum F2, and cylindrical surface C1. With reference to Figure 8, the anchors 30 are illustrated as being bounded by a second compound surface of revolution SR2 about axis A by rotating one of the anchors 30 about axis A for 360 degrees. The second compound surface of revolution SR2 defined by the anchors 30 includes a third, fourth and fifth frustums F3, F4, and F5, respectively.

[0045] Several design parameters are believed to allow the preferred embodiments to achieve various advantages over the known filters. The various advantages include, for example, resisting migration of the filter 100 once installed, greater filter volume, and better concentricity with respect to the inner wall of the blood vessel. A number of design parameters may be adjusted to effect performance and fit characteristics of the filter, including, for example, the ratio of the volume V1 defined by the first surface of revolution SR1 to the volume V2 defined by the second surface of revolution SR2, which may be at least 0.92, preferably about 1.0, and most preferably about 0.99. Also, approximately 15% or more of the volume V2 may be surrounded by the volume V1, preferably at least 25% of the volume V2 may be surrounded by the volume V1, and most preferably, about 35% of the volume V2 may be surrounded by volume V1 so that the portion of volume V2 that is not surrounded by volume V1 (i.e., the volume of V1 outside the first volume V1), shown as volume V3 in Fig. 9, is about 0.4 cubic inches.

Also, it has been discovered that, in the preferred embodiments, as the cross-sectional area of the hook is increased, the filter 100 tends to resist dislodgement when installed in a simulated blood vessel. Similarly, when the radius of curvature R_2 is decreased, while keeping other parameters generally constant, the resistance to dislodgement in a simulated blood vessel is increased.

[0046] The material for the filter may be any suitable bio-compatible material such as, for example, polymer, memory polymer, memory metal, thermal memory material, metal, metal alloy, or ceramics. Preferably, the material may be Elgiloy, and most preferably Nitinol which is a thermal shape memory alloy.

[0047] The use of a shape memory material, such as Nitinol, for the locator and anchor members facilitates collapsing the filter radially inward from its normally expanded (i.e., unconstrained) configuration toward its longitudinal axis into a collapsed configuration for insertion into a body vessel. The properties of Nitinol allow the filter members to withstand enormous deformations (e.g. 8 times as much as stainless steel) without having any effect of the filter ability to recover to the pre-determined shape. This is due to the crystal phase transitions between rigid austenite and softer martensite. This phenomenon enables the implant to be loaded into a very small diameter sheath for delivery, which significantly reduces the trauma and complications to the insertion site.

[0048] Transition between the martensitic and austenitic forms of the material can be achieved by increasing or decreasing the material deformation above and below the transition stress level while the material remains above the transition temperature range, specifically Af. This is particularly important in the case of the hooks, as they may be deformed significantly (hence, becoming martensitic) while the filter is challenged by clots. The super-elastic properties will allow the hooks to re-assume their intended shape as soon as the load is released (e.g. the clot breaks down).

[0049] The hooks may be retrieved from the Inferior Vena Cava ("IVC") wall during the filter removal when longitudinal force is applied to the hub 10 in the direction of the BF

(i.e., towards the hub 10 of the filter). Under this concentrated stress, the hooks will straighten and transition to the martensitic state, thereby becoming super-elastic. Thus the hooks 40 are designed to bend toward a substantially straight configuration when a specific hook migration force is applied and spring back to their original shape once the hook migration force is removed.

[0050] Alternatively, a reduction in temperature below the Af temperature can be applied to the shape memory material to cause a change in the crystalline phase of the material so as to render the material malleable during loading or retrieval of the filter. Various techniques can be used to cause a change in crystalline phase such as, for example, cold saline, low temperature fluid or thermal conductor.

[0051] By virtue of the characteristics of thermal shape memory material, the locator and anchor members can be cooled below the martensitic-to-austenitic transition temperature, and then straightened and held in a collapsed, straight form that can pass through a length of fine plastic tubing with an internal diameter of approximately 2 millimeters (mm), e.g., a #8 French catheter. In its high temperature form (as in a mammalian body), the filter 10 recovers to a preformed filtering shape as illustrated by Figure 1. Alternatively, the locator and/or anchor members may be made of wires of spring metal which can be straightened and compressed within a catheter or tube and will diverge into the filter shape of Figure 1 when the tube is removed.

[0052] The deployed shapes and configurations of the filter members can be set (imprinted with a memory shape) by annealing the members at high temperature (e.g. approximately 500°C) while holding them in the desired shape. Thereafter, whenever the filter is in the austenitic form (i.e., at a temperature above the martensitic-to-austenitic transition temperature or Af temperature), the members return to the memory shape. Example methods for setting the high-temperature shape of filters are disclosed in U.S. Patent No. 4,425,908.

[0053] In the high-temperature form of the shape memory material, the filter has generally coaxial first and second filter baskets or sieves, each filter basket being generally symmetrical about the longitudinal axis of the filter with both filter baskets being concave relative to the filter leading end.

[0054] The sieve V2 formed by anchor members 30 is the primary filter and can be up to twelve circumferentially spaced anchor members 30. Six anchor members 30 are shown in the embodiment illustrated in the figures. The anchor members may be of equal length, but may be of different length so that the hooks 40 at the ends of the wires will fit within a catheter without becoming interconnected. The anchor members 30, in their expanded configuration illustrated in Figure 1 (i.e., unconstrained in the high temperature form), are at a slight angle to the vessel wall, preferably within a range of from ten to forty-five degrees, while the hooks 40 penetrate the vessel wall to anchor the filter against movement. The anchor members 30 are radially offset relative to the locator members 20 and may be positioned radially halfway between the locator members 20 and also may be circumferentially spaced by sixty degrees of arc as shown in Figure 3. The locator members 20 form sieve V1. Thus, the combined filter sieves V2 and V1 can provide a wire positioned radially about the hub 10, such as at every thirty degrees of arc at the maximum divergence of the filter sections. With reference to the direction of blood flow BF shown by the arrow in Figures 2 and 4A, in the illustrated embodiment, the filter section V2 forms a frustum toward the hub 10 of the filter 100 while the filter section V1 forms a generally frustum-like concave sieve with its geometric center proximate the terminal end 12 of the hub 10. In the preferred embodiments, the volume V1 of the surface SR1 may be between about 0.3 and about 1.1 cubic inches, preferably about 0.7 cubic inches and the volume V2 of the surface SR2 may be between about 0.3 and about 1.1 cubic inches, preferably about 0.7 cubic inches.

[0055] The structure of the hooks 40 is believed to be important in resisting migration of the filter once installed while allowing for removal from the blood vessel after installation. As in the case of hooks formed on the anchor members of known permanent

vena cava filters, these hooks 40 penetrate the vessel wall when the filter 100 is expanded to anchor the filter in place and prevent filter migration longitudinally within the vessel in either direction. However, when the hooks 40 are implanted and subsequently covered by the endothelium layer, they and the filter can be withdrawn without risk of significant injury or rupture to the vena cava. Minor injury to the vessel wall due to hook withdrawal such as damage to the endothelial layer or local vena cava wall puncture is acceptable.

[0056] To permit safe removal of the filter, the juncture section 40S may be considerably reduced in cross section relative to the thickness t2 or cross section of the anchor member 30 and the remainder of the hook 40. The juncture section 40S can be sized such that it is of sufficient stiffness when the anchor members 30 are expanded to permit the hook 40 to penetrate the vena cava wall. However, when the hook is to be withdrawn from the vessel wall, withdrawal force in the direction of blood flow BF will cause flexure in the juncture section 40S so that the hook tip 40T moves toward a position parallel with the axis A (i.e., the hook straightens). With the hooks so straightened, the filter can be withdrawn without tearing the vessel wall while leaving only small punctures. In an embodiment, the anchor member 30 has a cross-sectional area of about 0.00013 squared inches, and the hook 40, particularly the curved junction section 40S has a cross-sectional area of about 0.000086 squared inches.

[0057] With reference to Figure 6, it will be noted that the entire hook 40 can be formed with a cross section t3 throughout its length that is less than that of the locator 20 members (which have thickness t1) or anchor members 30 (which have thickness t2). As a result, an axial withdrawal force will tend to straighten the hook 40 over its entire length. This elasticity in the hook structure is believed to prevent the hook from tearing the vessel wall during withdrawal.

[0058] As previously indicated, while it is possible that the filter could be made from ductile metal alloys such as stainless steel, titanium, or Elgiloy, it is preferable to make it from Nitinol. Nitinol is a low modulus material that allows the locator and anchor

members of the device 100 to be designed to have low contact forces and pressures while still achieving sufficient anchoring strength to resist migration of the device. The force required to cause opening of the hooks 40 can be modulated to the total force required to resist filter migration. This is accomplished by changing the cross sectional area or geometry of the hooks, or by material selection, as discussed above.

[0059] In addition to temperature sensitivity, when in the high temperature austenitic state, Nitinol is also subject to stress sensitivity that can cause the material to undergo a phase transformation from the austenitic to the martensitic state while the temperature of the material remains above the transition temperature. By reducing the cross sectional area of a portion or all of the hooks 40 relative to that of the anchor members 30 or locator members 20, stress will be concentrated in the areas of reduced cross section when longitudinal force is applied to the hub 10 in the direction of the BF (i.e., towards the hub 10 of the filter) such as to remove the filter. Under this concentrated stress, the reduced cross section portions of the hooks may transition to the martensitic state, thereby becoming elastic so that they straighten. Thus the hooks 40, whether formed of Nitinol, Elgiloy, spring metal or plastic, are designed to bend toward a substantially straight configuration when a specific hook migration force is applied and spring back to their original shape once the hook migration force is removed.

[0060] The force or stress that is required to deform the hooks 40 can be correlated to the force applied to each hook of the device when it is fully occluded and the blood pressure in the vessel is allowed to reach 50 millimeters of mercury (mm Hg) in a test stand. The test stand (not shown) can be configured to have a length of tubing (with various internal diameters) to allow a filter to be suitably attached thereto. The tubing is connected to another tubing having a terminal end exposed to ambient atmosphere and marked with gradations to indicate the amount of pressure differential across the filter, which is related to the force being applied to each locator of the filter 100. This force is approximately at least 70 grams on each anchor of a six-anchor device for at least 50 millimeters Hg pressure differential in a 28 mm vessel. The desired total migration resistance force for

the filter is believed to be approximately 420 grams for the embodiment of a vena cava filter for an adult human subject, and more anchor members 30 with hooks 40 can be added to lower maximum migration force for each hook. The load on the filter would be correspondingly smaller in vessels of smaller diameter. Preferably the hooks 40 perform as an anchoring mechanism at a predetermined filter migration resistance force within a range of about 10 mm Hg up to about 150-200 mm Hg. Having maintained its geometry at a predetermined filter migration resistance force within this range, the hook 40 preferably begins to deform in response to a higher force applied in the direction of the hub, i.e., the filter trailing end TE with respect to blood flow, and release at a force substantially less than that which would cause damage to the vessel tissue. It is the ability of the hook to straighten somewhat that allows for safe removal of the preferred embodiment filters from the vessel wall.

[0061] After the filter 100 has remained in place within a blood vessel for a period of time in excess of two weeks, the endothelium layer will grow over the hooks 40. However, since these hooks 40, when subjected to a withdrawal force in the direction of the hub (i.e., toward the trailing end TE) become substantially straight sections of wire oriented at a small angle to the vessel wall, the filter can be removed leaving only six pin point lesions in the surface of the endothelium. To accomplish this, a catheter such as, for example, the unit described and shown in U.S. Patent No. 6,156,055, or similar retrieval unit inserted over the hub 10 and into engagement with the locator members 20. While the hub 10 is held stationary, the stationary, the catheter may be moved downwardly, forcing the locator members 20 to fold towards the axis A, and subsequently engaging the anchor members 30 and forcing them downwardly thereby withdrawing the hooks 40 from the endothelium layer. Then the hub 10 may be drawn into the catheter to collapse the entire filter 100 within the catheter. When the filter is formed from shape memory material, cooling fluid (e.g., chilled saline) may be passed through the catheter during these steps to aid in collapsing the filter.

[0062] The primary objective of the hooks 40 is to ensure that the filter does not migrate during normal respiratory function or in the event of a massive pulmonary embolism. Normal inferior vena cava (IVC) pressures are believed to be between about 2 and about 5 mm Hg. An occluded IVC can potentially pressurize to 35 mmHg below the occlusion. To ensure filter stability, a 50 mm Hg pressure drop across the filter may therefore be chosen as the design criteria for the filter migration resistance force for the removable filter 100. When a removal pressure is applied to the filter that is greater than at least 50 millimeters Hg, the hooks 40 will deform and release from the vessel wall. The pressure required to deform the hooks can be converted to force by the following calculations.

Since 51.76 mm Hg = 1.0 pounds per square inch (psi),

$$50 \text{ mm Hg} = 0.9668 \text{ psi.}$$

For a 28 mm vena cava:

$$A = \frac{\pi}{4}(28)^2 \text{ mm}^2 = 615.4 \text{ mm}^2 = 0.9539 \text{ inches}^2$$

Migration force is calculated by:

$$P = \frac{F}{A} \qquad F = P \times A$$

$$0.9668 \text{ psi} \times 0.9539 \text{ inches}^2 = 0.9223 \text{ pounds} = 418.7 \text{ grams.}$$

[0063] It should be noted that as the vena cava diameter increases, so does the force required to resist at least 50 millimeters Hg of pressure.

[0064] Depending on the number of filter hooks 40, the required strength of each hook can be calculated. For a device that has six hooks:

$$\text{Hook Strength} = \frac{\text{Filter Migration Resistance Force}}{\text{Number of Hooks}}$$

$$= \frac{418.7}{6} = 69.7 \text{ grams}$$

[0065] In other words, each hook must be capable of resisting approximately at least 70 grams of force for the filter 100 to resist at least 50 millimeters Hg pressure gradient in a 28 mm diameter vessel.

[0066] To prevent excessive vessel trauma each individual hook needs to be relatively weak. By balancing the number hooks and the individual hook strength, minimal vessel injury can be achieved while still maintaining the at least 50 millimeters Hg pressure gradient criteria, or some other predetermined pressure gradient criteria within a range of from 10 mmHg to 150 mm Hg.

[0067] Referring to Figure 4A, the anchor members 30 may be angled outwardly from the anchor joint or bend AJ1 adjacent to but spaced from the outer end of each anchor member 30. When the anchor members 30 are released from compression in a catheter or other tube into a body vessel, this bend in each anchor member insures that the hooks 40 are, in effect, spring loaded in the tube and that they will not cross as they are deployed from the tube. Since the anchor members 30 angled outwardly from the shoulders 30, the hooks 40 are rapidly deployed outwardly as the insertion tube is withdrawn.

[0068] In another embodiment, bio-active agents can be incorporated with the blood filter, such as by way of a coating on parts of the filter, or dissolvable structures on, within or attached to the filter. Bio-active agent may be included as part of the filter in order to treat or prevent other conditions (such as infection or inflammation) associated with the filter, or to treat other conditions unrelated to the filter itself. More specifically, bio-active agents may include, but are not limited to: pharmaceutical agents, such as, for example, anti-proliferative/antimitotic agents including natural products such as vinca alkaloids (i.e. vinblastine, vincristine, and vinorelbine), paclitaxel, epidipodophyllotoxins (i.e. etoposide, teniposide), antibiotics (dactinomycin (actinomycin D) daunorubicin, doxorubicin and idarubicin), anthracyclines, mitoxantrone, bleomycins, plicamycin (mithramycin) and mitomycin, enzymes (L-asparaginase which systemically metabolizes L-asparagine and deprives cells which do not have the capacity to synthesize their own asparagine);

antiplatelet agents such as G(GP) IIb/IIIa inhibitors and vitronectin receptor antagonists;

anti-proliferative/antimitotic alkylating agents such as nitrogen mustards (mechlorethamine, cyclophosphamide and analogs, melphalan, chlorambucil), ethylenimines and methylmelamines (hexamethylmelamine and thiotepa), alkyl sulfonates-busulfan, nirtosoureas (carmustine (BCNU) and analogs, streptozocin), and trazenes - dacarbazinine (DTIC);

anti-proliferative/antimitotic antimetabolites such as folic acid analogs (methotrexate), pyrimidine analogs (fluorouracil, floxuridine, and cytarabine), purine analogs and related inhibitors (mercaptopurine, thioguanine, pentostatin and 2-chlorodeoxyadenosine {cladribine});

platinum coordination complexes (cisplatin, carboplatin), procarbazine, hydroxyurea, mitotane, aminoglutethimide;

hormones (i.e. estrogen);

anti-coagulants (heparin, synthetic heparin salts and other inhibitors of thrombin);

fibrinolytic agents (such as tissue plasminogen activator, streptokinase and urokinase), aspirin, dipyridamole, ticlopidine, clopidogrel, abciximab;

antimigratory agents;

antisecretory agents (e.g., breveldin);

anti-inflammatory agents, such as adrenocortical steroids (cortisol, cortisone, fludrocortisone, prednisone, prednisolone, 6α-methylprednisolone, triamcinolone, betamethasone, and dexamethasone), non-steroidal agents (salicylic acid derivatives i.e. aspirin;

para-aminophenol derivatives i.e. acetominophen;

indole and indene acetic acids (indomethacin, sulindac, and etodalac), heteroaryl acetic acids (tolmetin, diclofenac, and ketorolac), arylpropionic acids (ibuprofen and derivatives), anthranilic acids (mefenamic acid, and meclofenamic acid), enolic acids (piroxicam, tenoxicam, phenylbutazone, and oxyphenthatrazone), nabumetone, gold compounds (auranofin, aurothioglucose, gold sodium thiomalate);

immunosuppressives: (cyclosporine, tacrolimus (FK-506), sirolimus (rapamycin), azathioprine, mycophenolate mofetil);

angiogenic agents, such as vascular endothelial growth factor (VEGF), fibroblast growth factor (FGF);

angiotensin receptor blockers;

nitric oxide donors;

anti-sense oligionucleotides and combinations thereof;

cell cycle inhibitors, such as mTOR inhibitors, and growth factor receptor signal transduction kinase inhibitors;

retenoids;

cyclin/CDK inhibitors;

HMG co-enzyme reductase inhibitors (statins); and

protease inhibitors.

[0069] A filter delivery unit (not shown) such as, for example, the unit described in U.S. Patent No. 6,258,026, is adapted to deliver the filter 100 through a catheter or delivery tube to a generally centered position within a body vessel. Preferably, the delivery system may be the delivery system shown and described in a PCT Patent Application entitled "Embolus Blood Clot Filter and Delivery System" and PCT application No. PCT/US2006/017890 filed on May 9, 2006.

[0070] In an embodiment, a radio-opaque material can be incorporated in a portion of the filter, preferably the hub 10 of the filter. As used herein, a radio-opaque material is any material that is identifiable to machine or human readable radiographic equipment while

the material is inside a mammal body, such as, by way of example but not by way of limitation, gold, tungsten, platinum, barium sulfate, or tantalum. The use of a radio-opaque material in the filter permits the clinician to locate the filter within a blood vessel of the subject using radiographic equipment. Radio-opaque material may be in the form of an additional structure added to the hub, such as a cap, sleeve, shim, wire or braze included around or in the hub assembly. Alternatively, the hub itself may be formed of a radio-opaque alloy.

[0071] Instead of a hub 10, as in the above described embodiments, a retrieving hook can be provided as part of filter device 200, as in the embodiment shown in Figure 10. The filter device 200 includes a hub 210 with a retrieving hook 220. The hook 220 is configured for use by a snaring device to retrieve the filter 200 from a subject. Referring to Figures 11 and 12, the retrieving hook 220 can be formed as a monolithic member 230 with the hub 210 or as a separate member joined to the hub 210 by a suitable technique, such as, for example, EDM, laser welding, plasma welding, welding brazing, welding, soldering, or bonding. In a preferred embodiment, the member 230 can be a machined billet member with a blind bore 240 formed through a portion of the hub 210. The hook portion 220 includes ramped surfaces 250 and 260 that are believed to be advantageous in allowing the filter 200 to be retrieved without binding at the catheter opening due to an offset entry position of the filter 200. In other words, there may be circumstances during removal procedures where the axis 300 of the member 230 is not generally parallel or aligned with a longitudinal axis of the catheter retrieving device. In such cases, the greater the retention force, it is believed that the greater the likelihood of the hook being snagged on the catheter inlet opening thereby complicating the filter retrieval process. By virtue of the ramps 250 and 260, it is believed that binding or snagging is substantially reduced. In particular, as shown in Figures 13 and 14, the ramp 250 includes a radius of curvature R4 coupled to flat portions 252 and 254. The flat portion 254 can be coupled to a hook portion 256 which has a radiused surface R6. As shown in Figure 13, the flat portion 252 is coupled to another radiused portion R7. It should be

noted that the drawings provided herein are to scale relative to every part illustrated in each drawing.

[0072] A range of values may be used for the aforementioned dimensional parameters in order to provide a retrieval hook 230 that is capable of retaining portions of the locator and anchor members 20 and 30 within blind hole 240. For example, a smaller filter may have smaller dimensions so that the retrieval hook 230 does not present undue blockage in the vein, than a filter intended to be placed in a large vein or vessels, such as an adult vena cava or other vessel. Further, the retrieval hook 230 may be made from or include a radio-opaque material to allow a clinician to locate the hook within a subject using radiographic equipment, such as to aid in engaging the hook with a retrieval mechanism.

[0073] While the present invention has been disclosed with reference to certain preferred embodiments, numerous modifications, alterations, and changes to the described embodiments are possible without departing from the sphere and scope of the present invention, as defined in the appended claims. Accordingly, it is intended that the present invention not be limited to the described embodiments, but that it have the full scope defined by the language of the following claims, and equivalents thereof.

What is claimed is:

1. A filter to be placed in a flow of blood through a vessel, the filter comprising:

a hub disposed along a longitudinal axis;

at least one anchor projecting from the hub, the at least one anchor member including a hook that penetrates a wall of the blood vessel when the filter is placed in the blood vessel, the hook being spaced along the longitudinal axis from the hub, and spaced a first radial distance from the longitudinal axis; and

at least one locator projecting from the hub, the at least one locator having a tip portion being spaced along the longitudinal axis from the hub and spaced a second radial distance from the longitudinal axis, the second radial distance being less than the first radial distance, the locator having at least four portions, each of the portions being disposed on respective distinct axes;

wherein a first segment of each said locator defines a first angle with respect to the longitudinal axis, a second segment of each said locator extends along a second angle with respect to the longitudinal axis, and a third segment portion of each locator extends along a third angle with respect to the longitudinal axis, the first angle being about 60 degrees, the second angle being about 20 degrees and the third angle being less than about 1 degree.

2. The filter according to claim 1, wherein the locator proximate the hub comprises a curved portion that extends along the longitudinal axis on a radius of curvature to define the first angle with respect to the longitudinal axis.

3. The filter of claim 1, wherein the hook is offset in alignment with respect to the axis on which at least one segment of the anchor member is aligned.

4. The filter of claim 1, wherein each of the plurality of anchor members comprises:

a first anchor segment that extends away from the longitudinal axis at a fourth angle;

a second anchor segment that extends away from the longitudinal axis at a fifth angle; and

a retention portion.

5. The filter of claim 4, wherein at least two of the plurality of locators define a first virtual circle having a first diameter extending through the longitudinal axis.

6. The filter of claim 5, wherein the locator comprises a hook to engage with the wall of the blood vessel.

7. The filter of claim 5, wherein at least two of the plurality of anchor members define a second virtual circle having a second diameter extending through the longitudinal axis, the second diameter being about 1.2 times the first diameter.

8. The filter of claim 7, wherein the end portion comprises a length along the longitudinal axis of about 0.05 inches.

9. The filter of claim 2, wherein the curved portion comprises a radius of curvature of about 0.1 inches about an axis generally orthogonal to the longitudinal axis.

10. The filter of claim 8, wherein the retention portion comprises a hook.

11. The filter of claim 10, wherein the hook comprises a curved configuration in an operative condition and a generally linear configuration in a constrained condition.

12. The filter of claim 11, wherein the hook comprises a curved configuration in an operative condition and an anchor member is twisted about its axis in a constrained condition of the filter.

13. The filter of claim 12, wherein the hook is in the constrained condition when at least about at least 70 grams of force or more is applied to each locator along the longitudinal axis.

14. The filter of claim 13, wherein the anchor segments comprise a cross-sectional area of about 0.00013 squared inches.

15. The filter of claim 14, wherein the hook comprises a curved member having a cross-sectional area of about 0.000086 squared inches.

16. The filter according to claim 15, wherein the hooks define a first circle having a radius equal to the first distance, and the tips define a second circle having a radius equal to the second distance, the first and second circles being generally concentric about the longitudinal axis.

17. The filter according to any one of claims 1 to 16, wherein each of the anchors comprises a first segment extending substantially parallel to the longitudinal axis, a second segment extending tangentially with respect to the respective hook, and an intermediate segment extending between and obliquely coupled to each of the respective first and second segments.

18. The filter according to claim 17, wherein each first, second and intermediate segment extend generally linearly.

19. The filter according to claim 18, wherein each first, second and intermediate segment extend curvilinearly.

20. The filter according to claim 19, wherein each of the second segments extends obliquely with respect to the long axis at a first angle, and each of the intermediate segments extends obliquely with respect to the long axis at a second angle less than the first angle.

21. The filter according to claim 20, wherein when the filter is in an unconstrained state:

the tip portion has a length along the longitudinal axis of about 0.05 inches;

a curved portion proximate the hub extending along the longitudinal axis comprises a radius of curvature of about 0.1 inches;

the first segment of the locator extends to about 0.4 inches from the longitudinal axis and about 0.3 inches from the hub measured along the longitudinal axis;

the second segment of the locator extends to about 0.75 inches from the longitudinal axis and about 0.9 inches from the hub measured along the longitudinal axis;

a portion of the hook on the anchor lies about 0.75 from the longitudinal axis and about 1.3 inches from the hub measured along the longitudinal axis; and

the hook comprises a radius of curvature of about 0.03 inches.

22. The filter according to claim 21, wherein the intermediate segments define a cone having a first apex located along the longitudinal axis proximate the hub.

23. The filter according to any one of claims 1 to 22, further comprising a bio-active agent.

24. The filter according to any one of claims 1 to 22, further comprising a bio-active agent coupled to the filter and a radiopaque material disposed proximate the hub.

25. A filter to be placed in a flow of blood through a vessel, the filter comprising:

a hub disposed along a longitudinal axis;

at least one anchor projecting from the hub, the at least one anchor member including a hook that penetrates a wall of the blood vessel when the filter is placed in the blood vessel, the hook being spaced along the longitudinal axis from the hub, and spaced a first radial distance from the longitudinal axis; and

at least one locator projecting from the hub, the at least one locator having a tip portion being spaced along the longitudinal axis from the hub and spaced a second radial distance from the longitudinal axis, the second radial distance being less than the first radial distance, the locator having at least four portions, each of the portions being disposed on respective distinct axes,

wherein, when the filter is in an unconstrained state:

the tip portion has a length along the longitudinal axis of about 0.05 inches;

a curved portion proximate the hub extending along the longitudinal axis comprises a radius of curvature of about 0.1 inches;

the first segment of the locator extends to about 0.4 inches from the longitudinal axis and about 0.3 inches from the hub measured along the longitudinal axis;

the second segment of the locator extends to about 0.75 inches from the longitudinal axis and about 0.9 inches from the hub measured along the longitudinal axis;

a portion of the hook on the anchor lies about 0.75 from the longitudinal axis and about 1.3 inches from the hub measured along the longitudinal axis; and

the hook comprises a radius of curvature of about 0.03 inches.

26. The filter according to claim 25, wherein each of the anchors comprises a first segment extending substantially parallel to the longitudinal axis, a second segment extending tangentially with respect to the respective hook, and an intermediate segment extending between and obliquely coupled to each of the respective first and second segments.

27. The filter according to claim 26, wherein each first, second and intermediate segment extend generally linearly.

28. The filter according to claim 27, wherein each first, second and intermediate segment extend curvilinearly.

29. The filter according to claim 28, wherein each of the second segments extends obliquely with respect to the long axis at a first angle, and each of the intermediate segments extends obliquely with respect to the long axis at a second angle less than the first angle.

30. A method of manufacturing a blood filter, the method comprising:

locating a plurality of locators about a longitudinal axis, each of the plurality of locators having an end portion, the locating comprising coupling each of the plurality of locators together to define a hub;

configuring the end portion to define a virtual cylinder about the longitudinal axis;

connecting a plurality of anchors to the plurality of locators, each of the plurality of anchors having a main portion coupled to a retention portion; and

orientating the main portion of the anchor to define a virtual cone about the longitudinal axis.

31. The method of claim 30, wherein locating a plurality of locators about a longitudinal axis comprises using the end portions of the locators comprising at least one of a hook and a stop member.

32. A method of manufacturing a blood filter, the method comprising:

locating a plurality of locators about a longitudinal axis, each of the plurality of locators having an end portion;

configuring the end portion to define a virtual cylinder about the longitudinal axis, the configuring comprising bending a wire into a curved segment, a middle segment and an end segment;

connecting a plurality of anchors to the plurality of locators, each of the plurality of anchors having a main portion coupled to a retention portion; and

orientating the main portion of the anchor to define a virtual cone about the longitudinal axis.

33. The method of claim 32, wherein the middle segment comprises a first length, the end segment of about six percent of the first length and the curved segment of about 21 percent of the first length.

34. The method of claim 32, wherein the orientating comprises forming a wire into first, second and third segments, the first segment connected to a hook, the first segment having a first segment length, the second segment having a length of about 450 percent of the first segment length, and the third segment of about 27 percent of the first segment length.

35. The method of claim 32, wherein orientating the main portion of the anchor comprises defining the virtual cone to comprise a generally circular base having a diameter of about 1.1 times a diameter of the virtual cylinder.

36. The method of claim 30, wherein locating a plurality of locators about a longitudinal axis comprises using the end portions of the locators comprising at least one of a hook and a stop member.

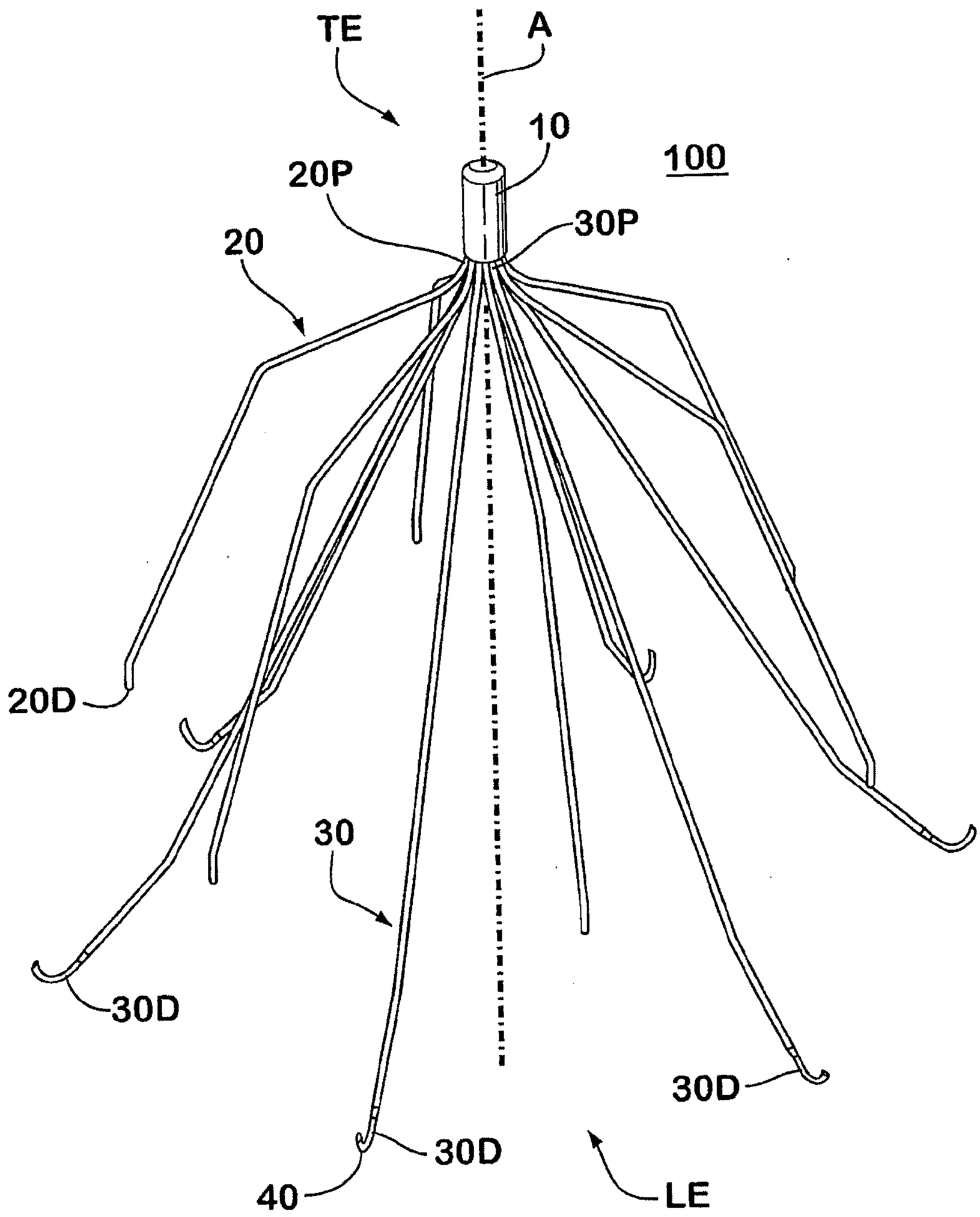


FIG. 1

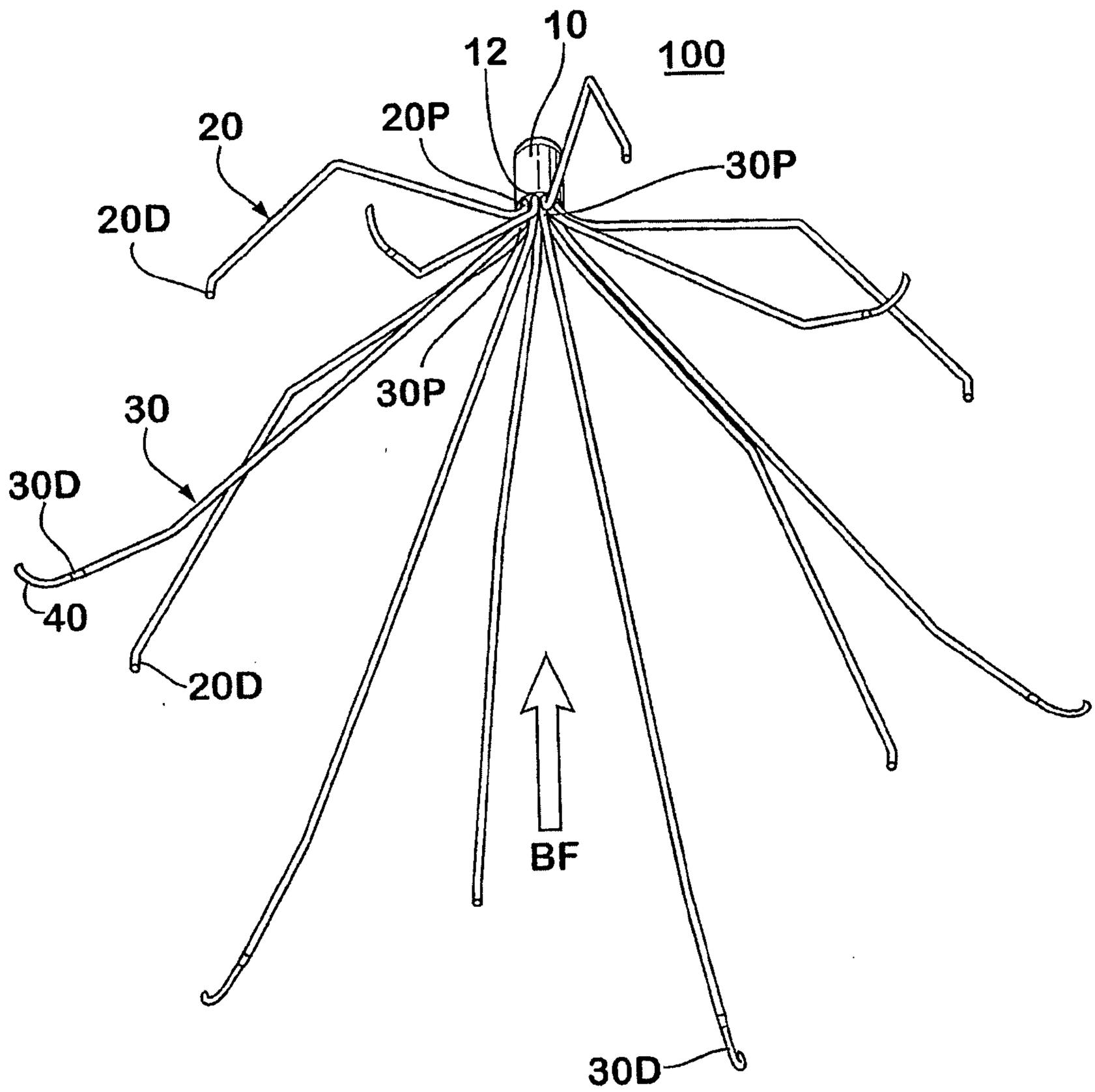


FIG.2

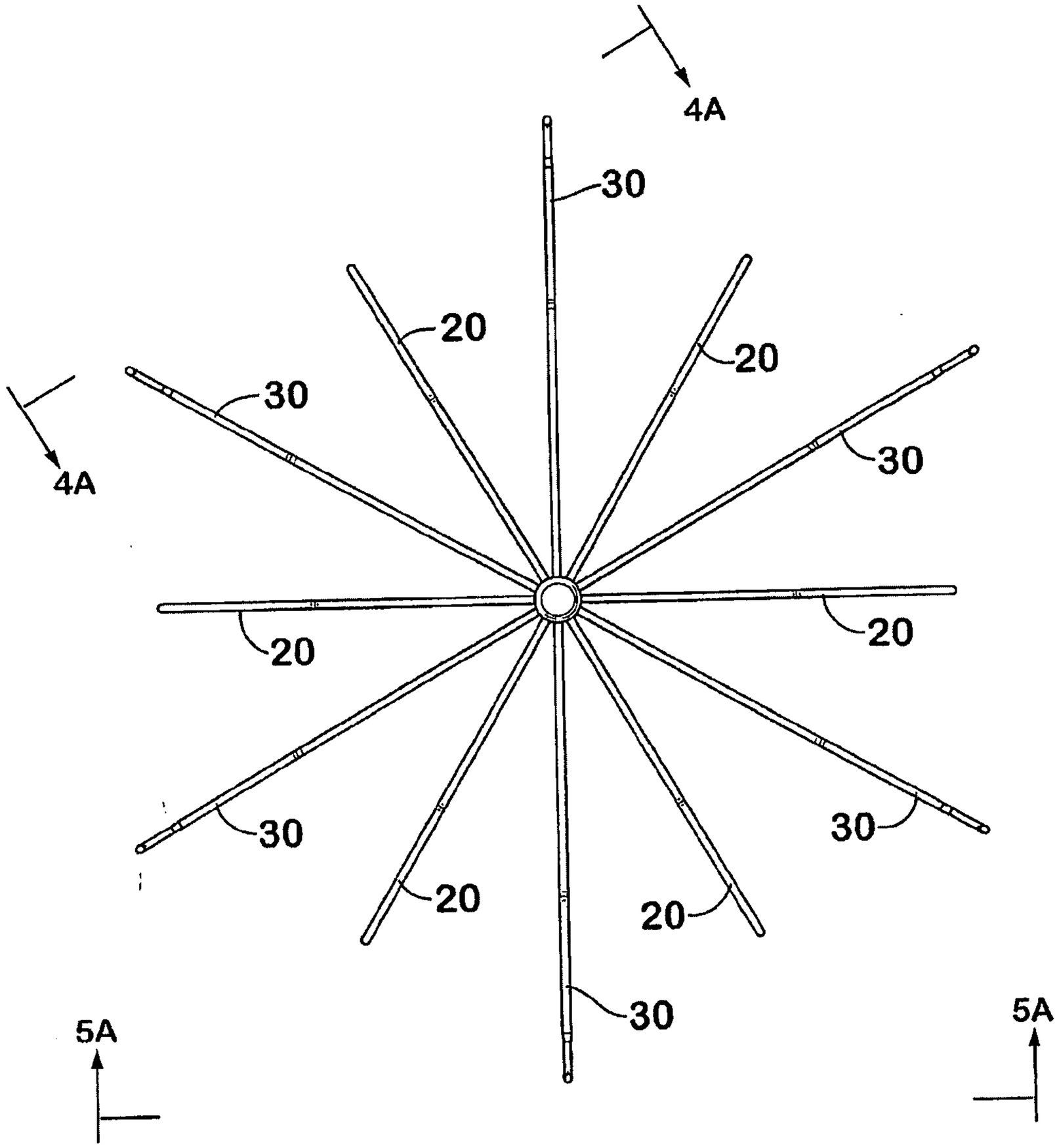
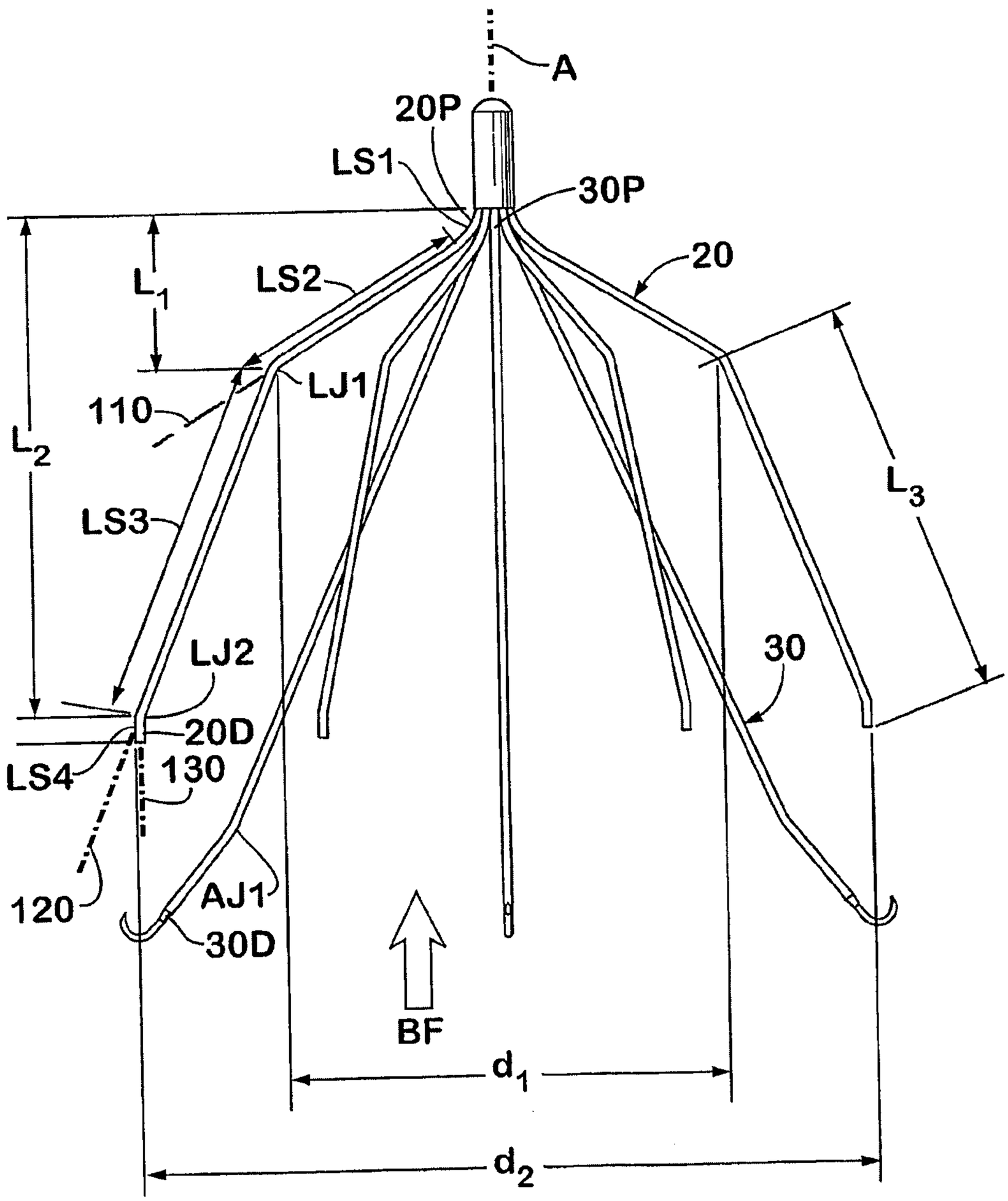


FIG.3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30P
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LS2
L_1
LJ1
110
L_2
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30
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d_2

FIG.4A

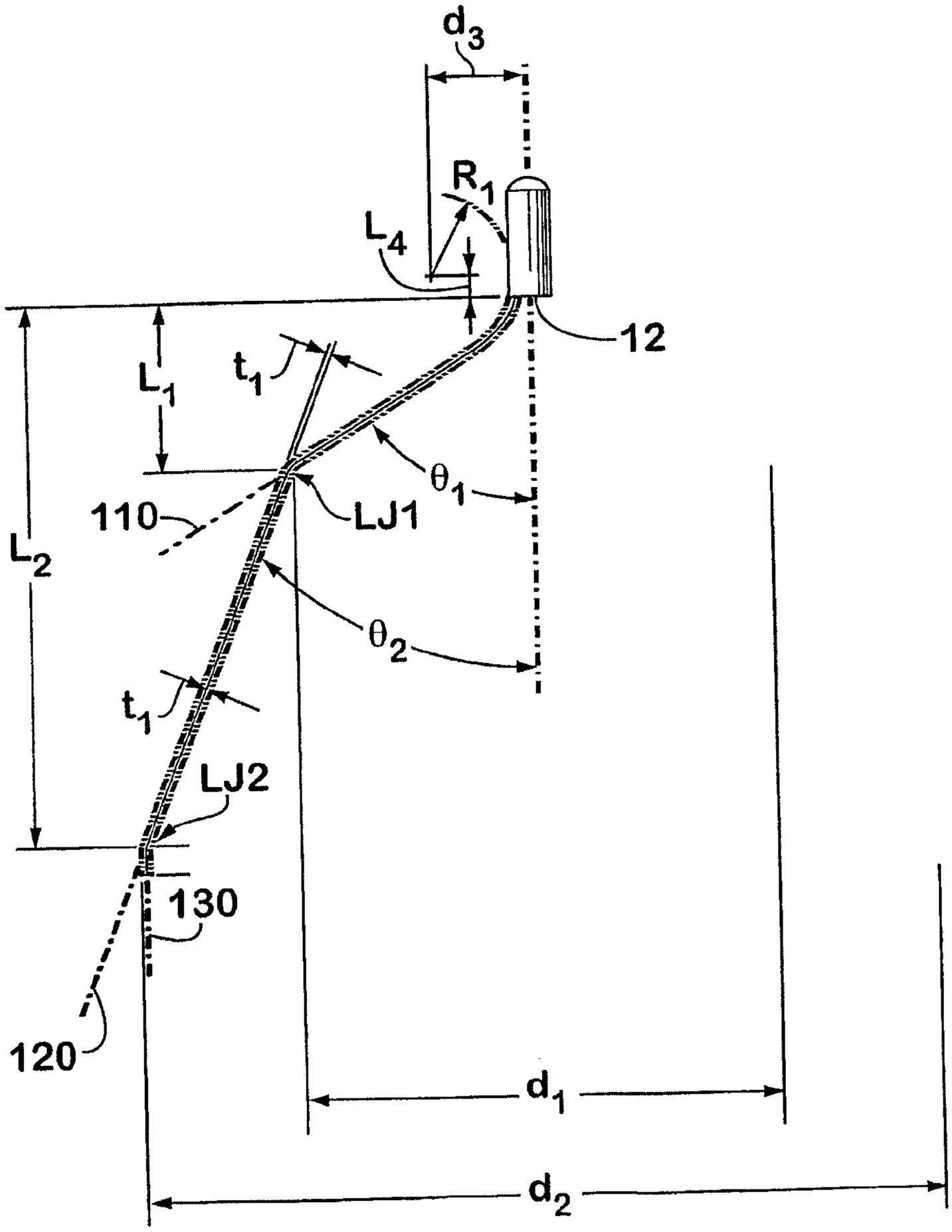


FIG.4B

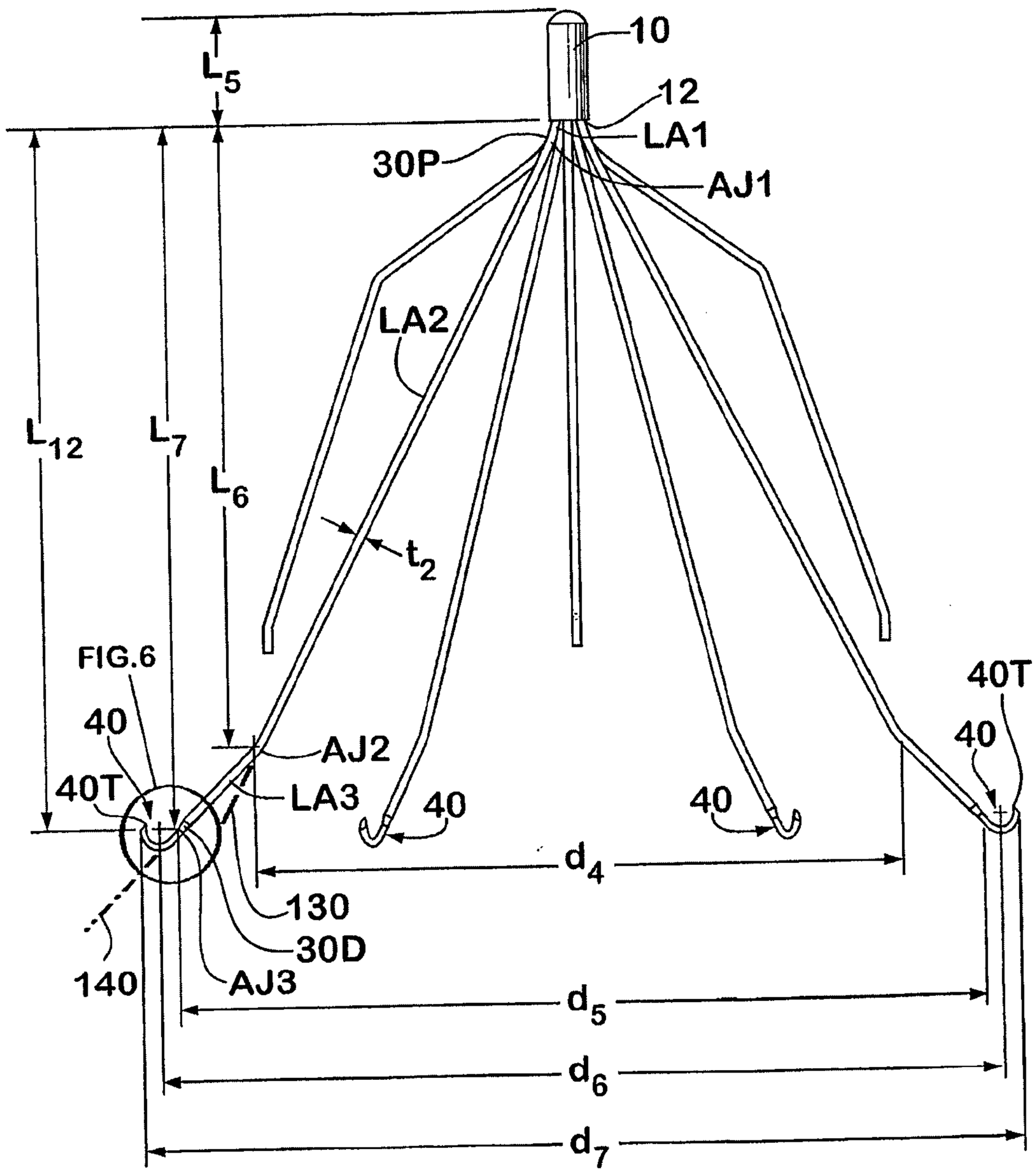

L5
10
12
LA1
30P
AJ1
LA2
L12
L7
L6
t2
40T
40
AJ2
LA3
40
40
40T
40
130
30D
140
AJ3
d4
d5
d6
d7

FIG.6

FIG.5A

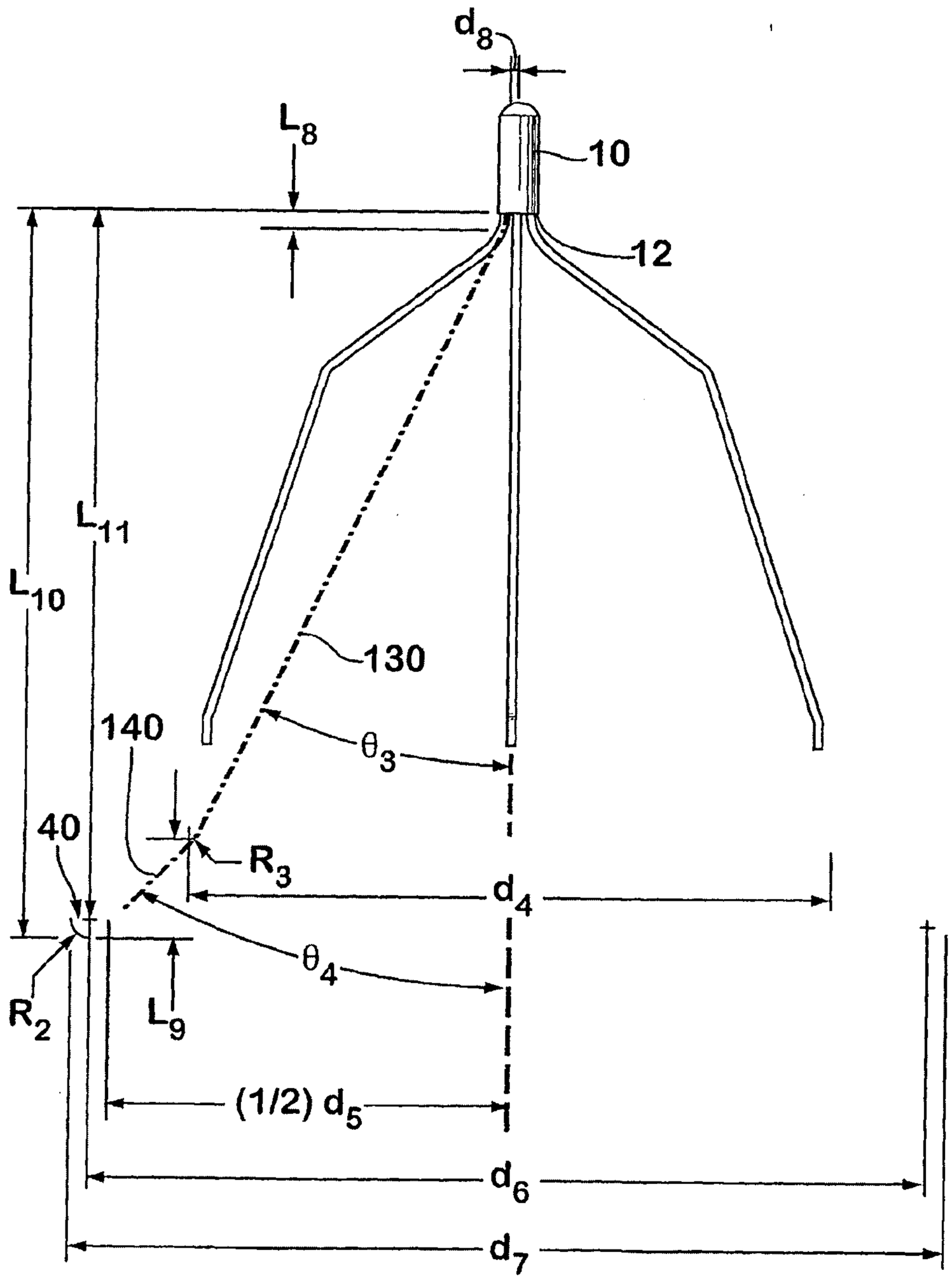

d_8
L_8
10
12
L_{11}
L_{10}
130
140
θ_3
40
R_3
d_4
θ_4
R_2
L_9
(1/2) d_5
d_6
d_7

FIG.5B

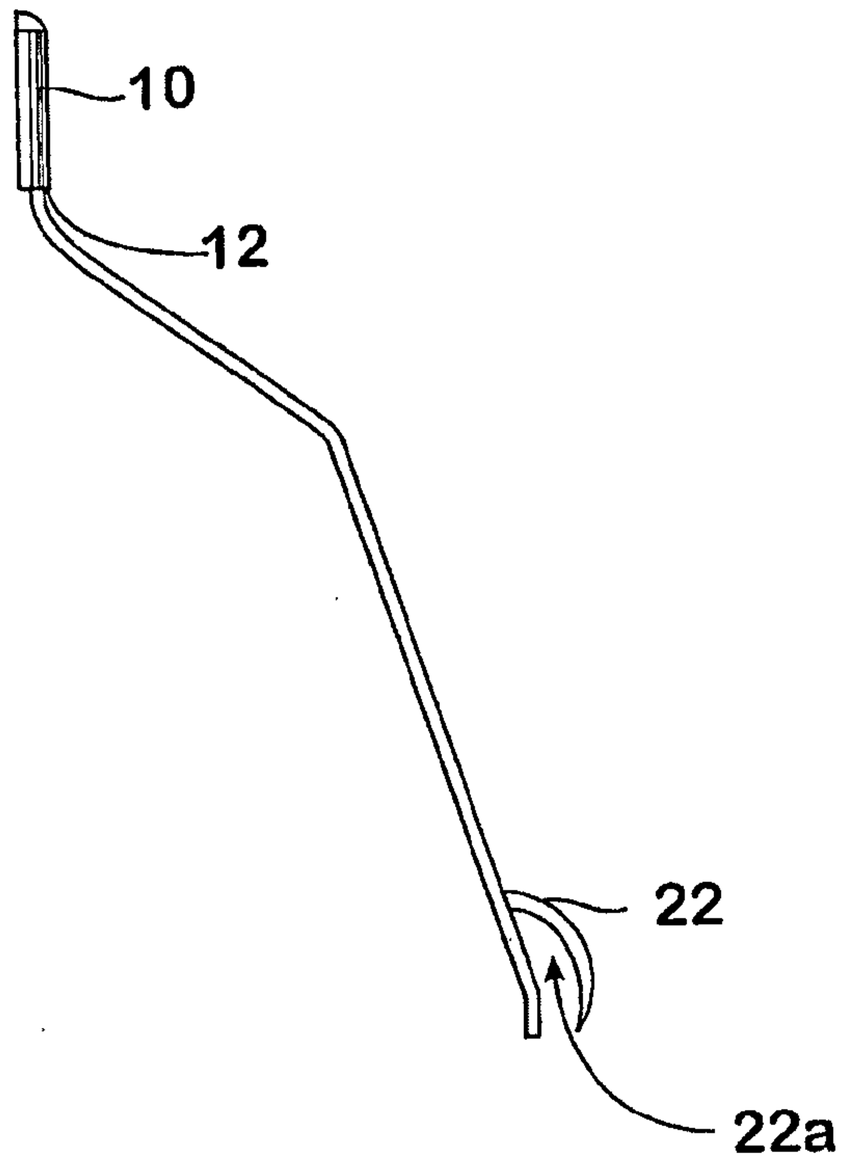


FIG.5C

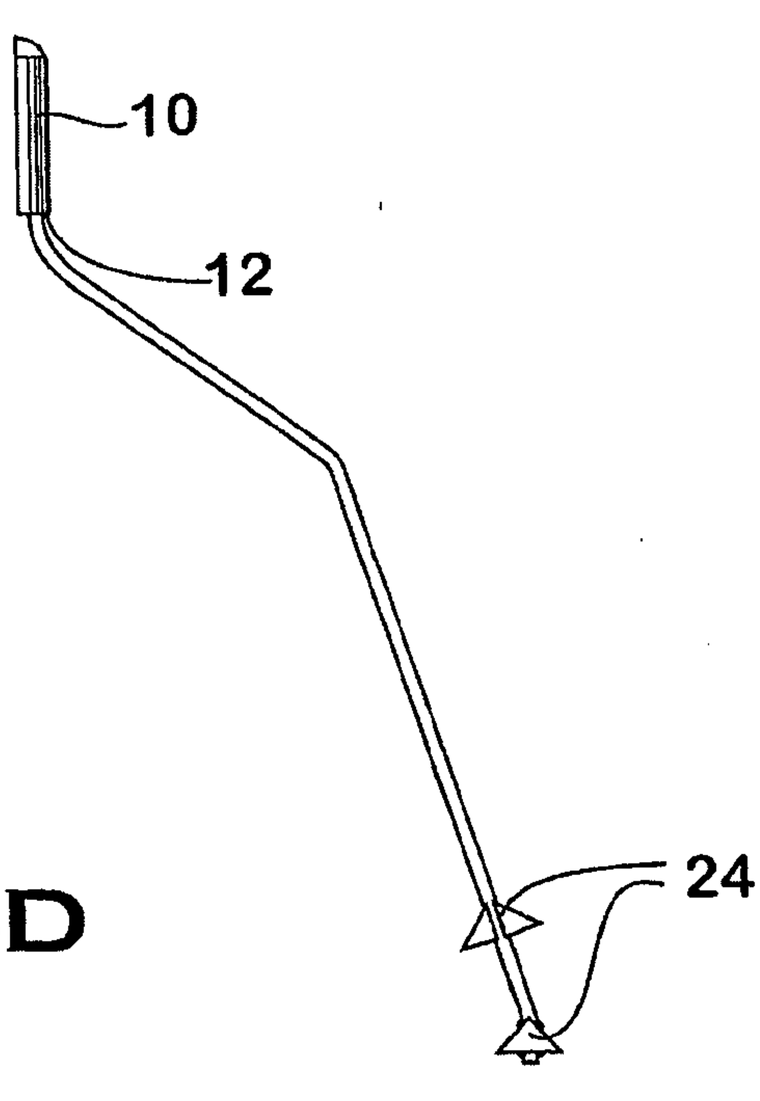
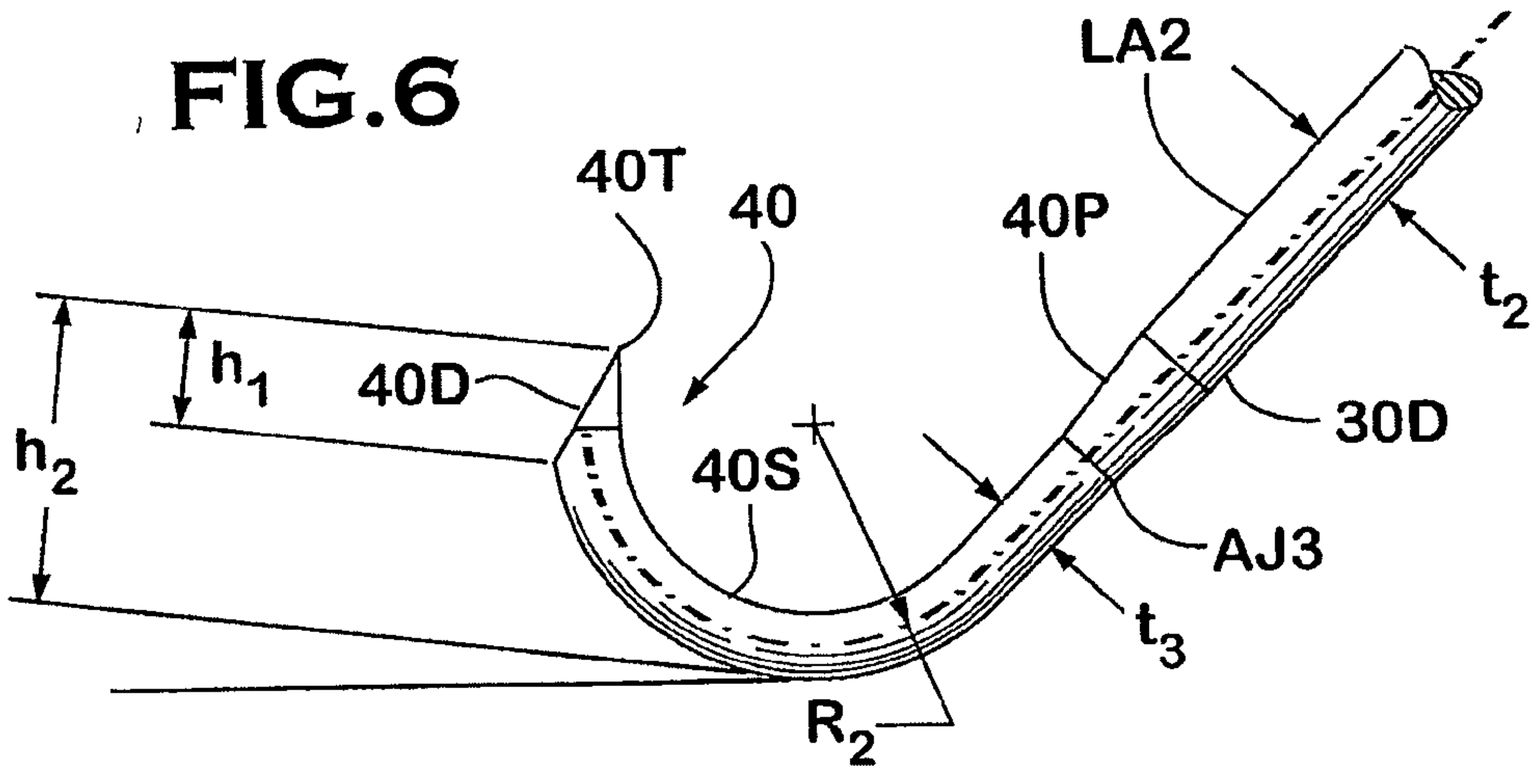


FIG.5D

FIG.6


40T
40
LA2
40P
t_2
h_1
40D
30D
h_2
40S
AJ3
t_3
R_2

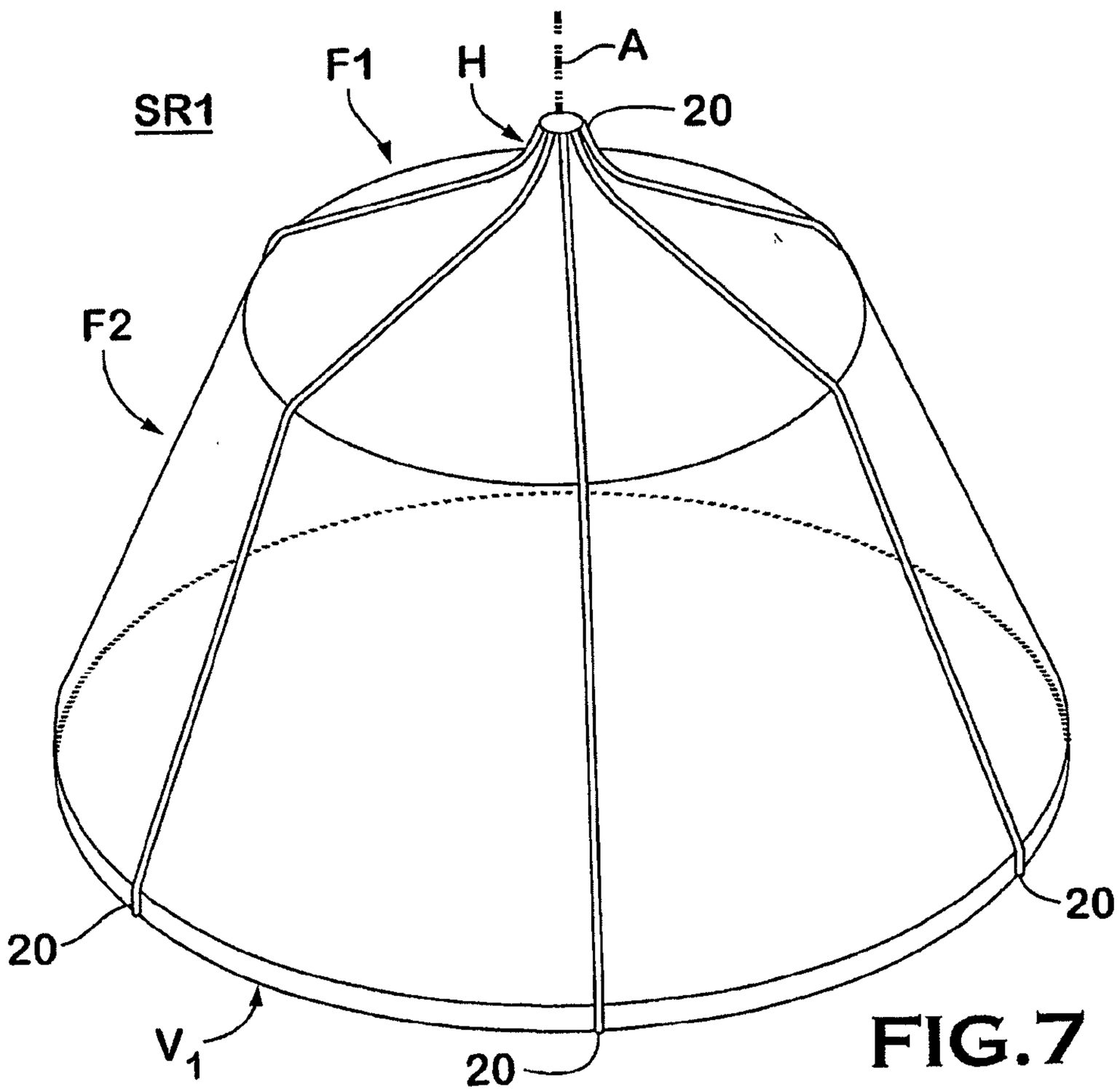

SR1
F1
H
A
20
F2
20
20
V_1
20

FIG.7

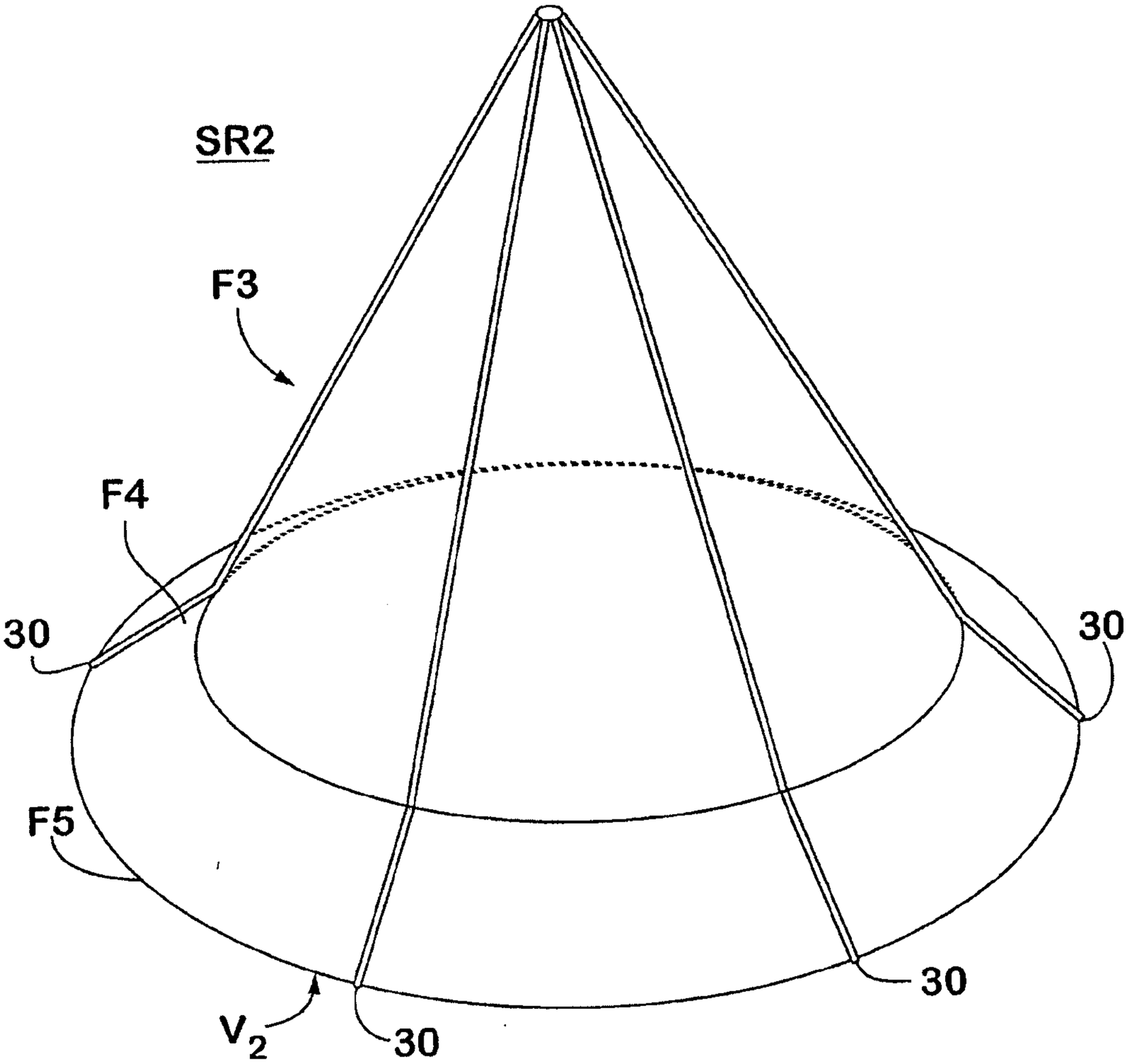


FIG.8

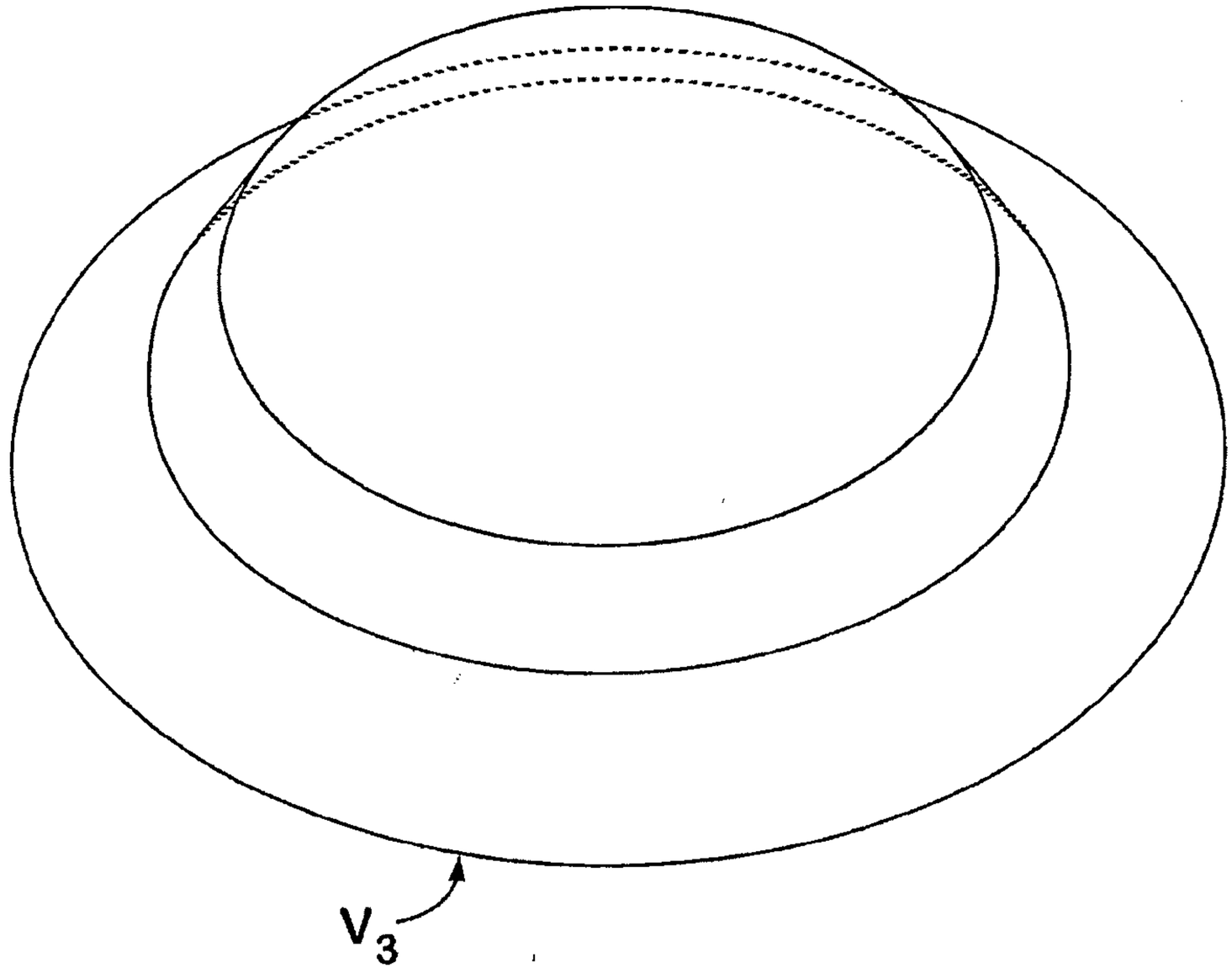


FIG.9

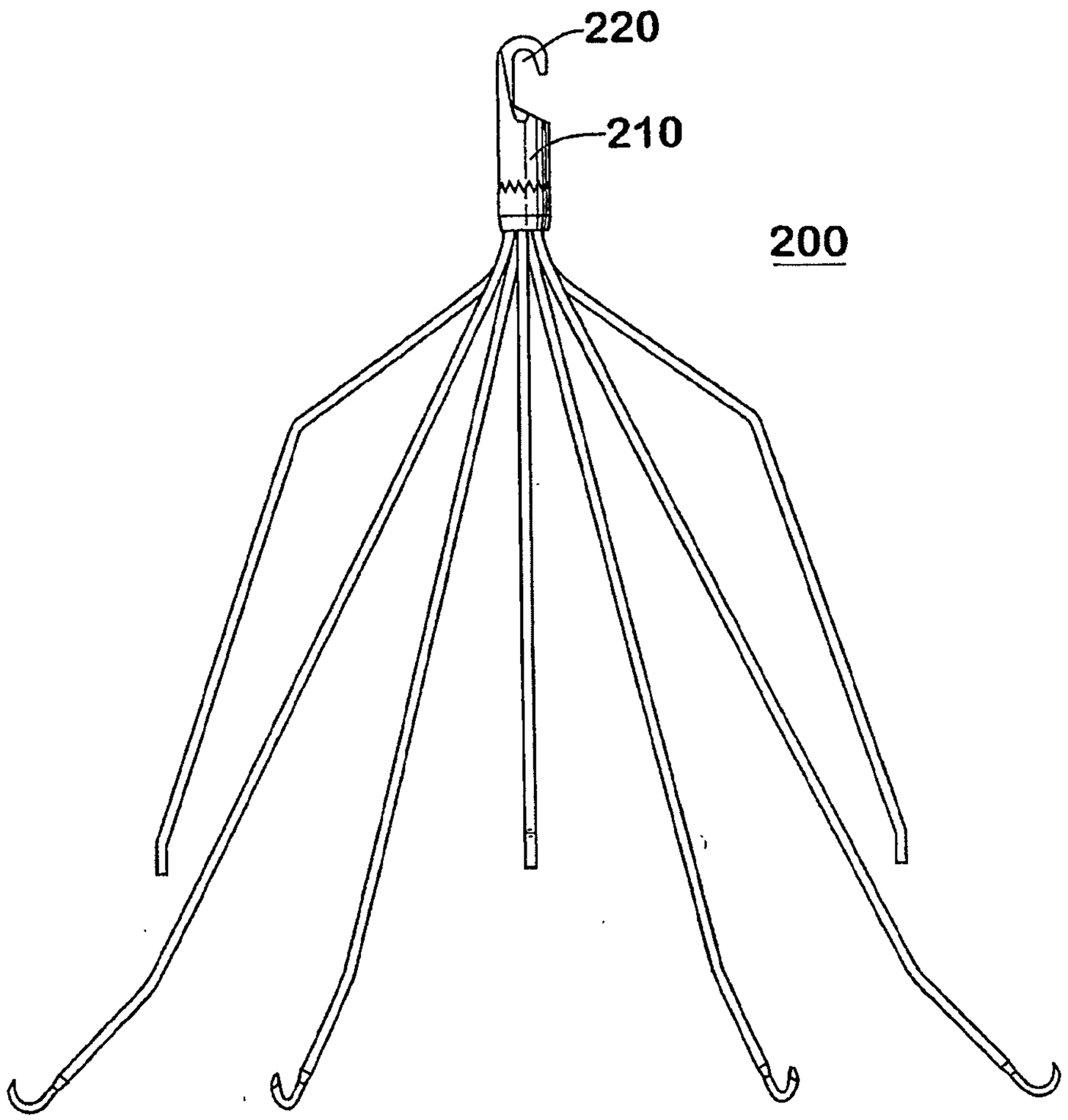


FIG. 10

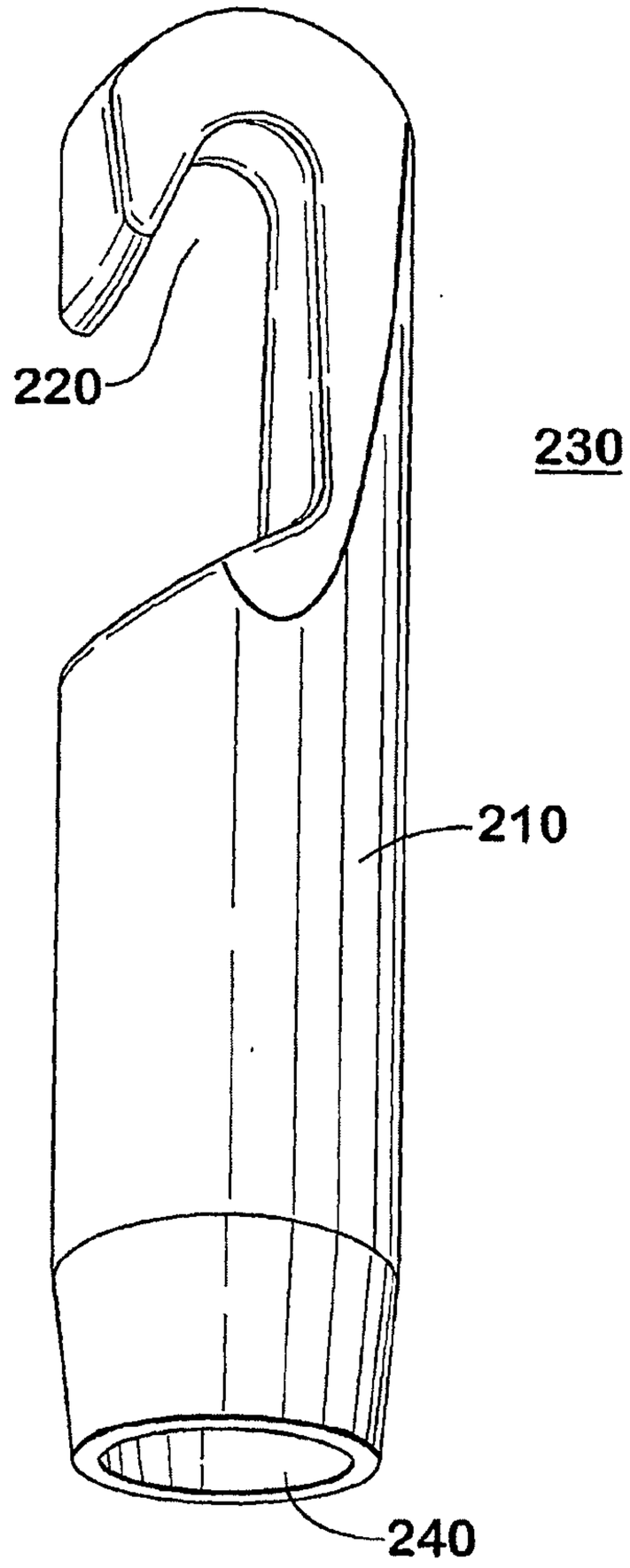


FIG. 11

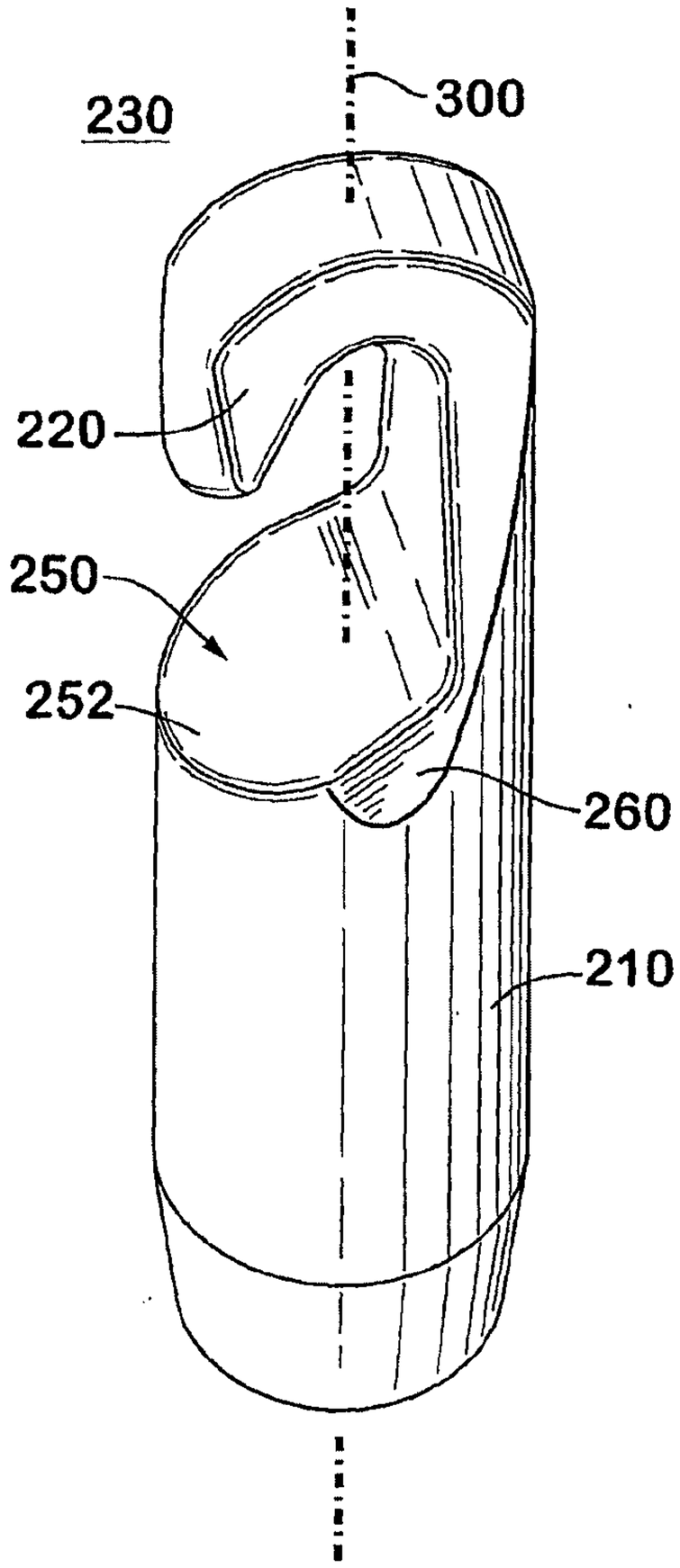


FIG. 12

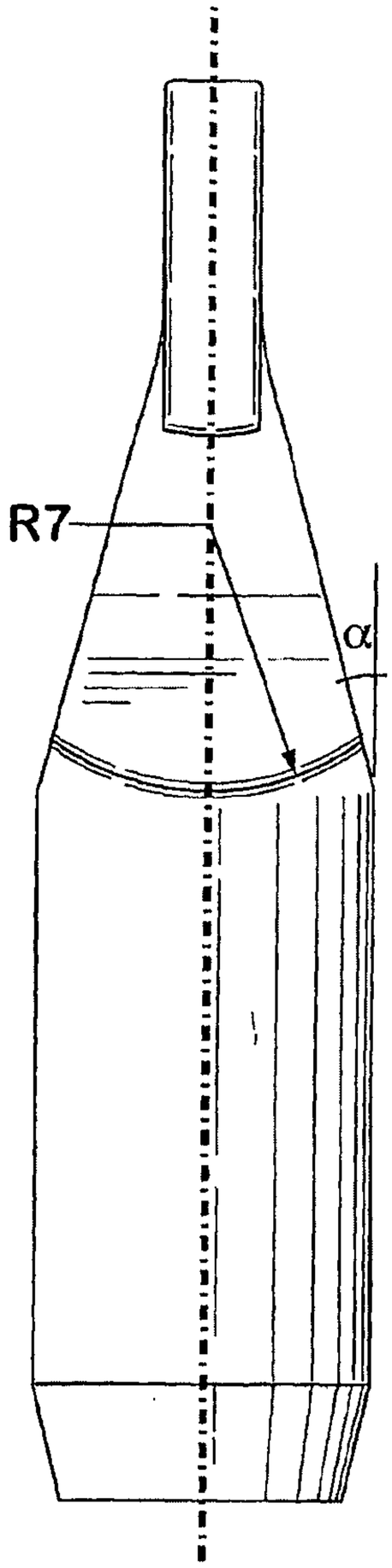


FIG. 13

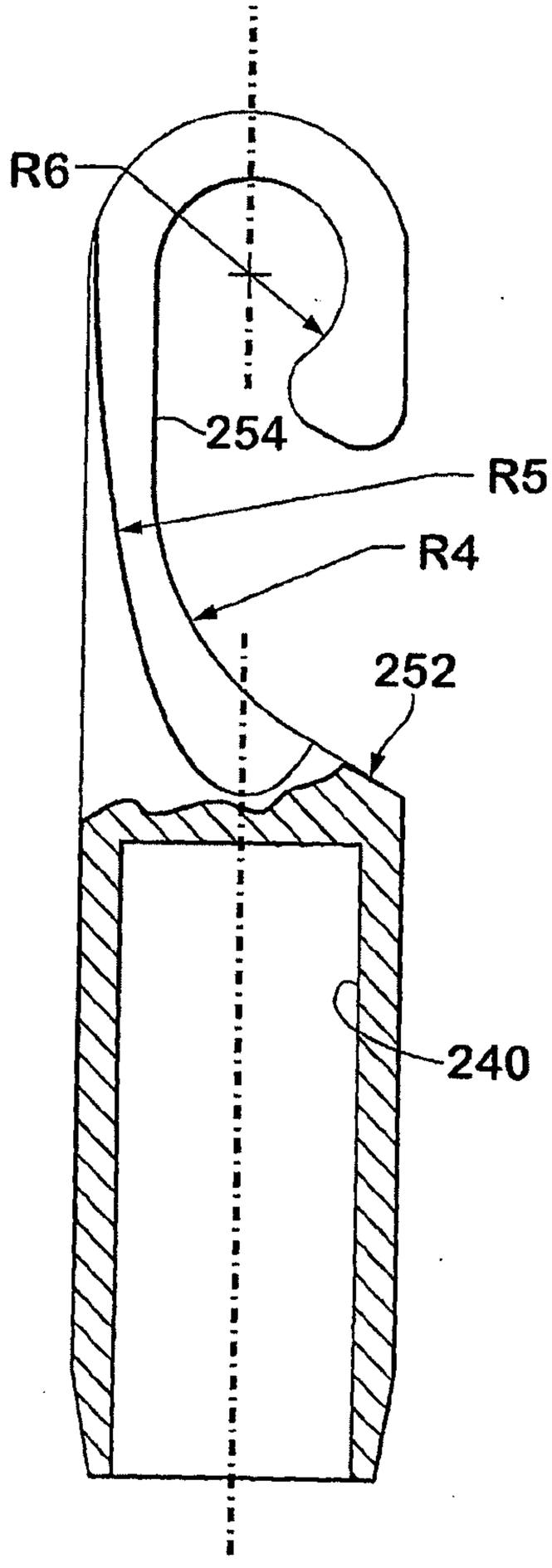
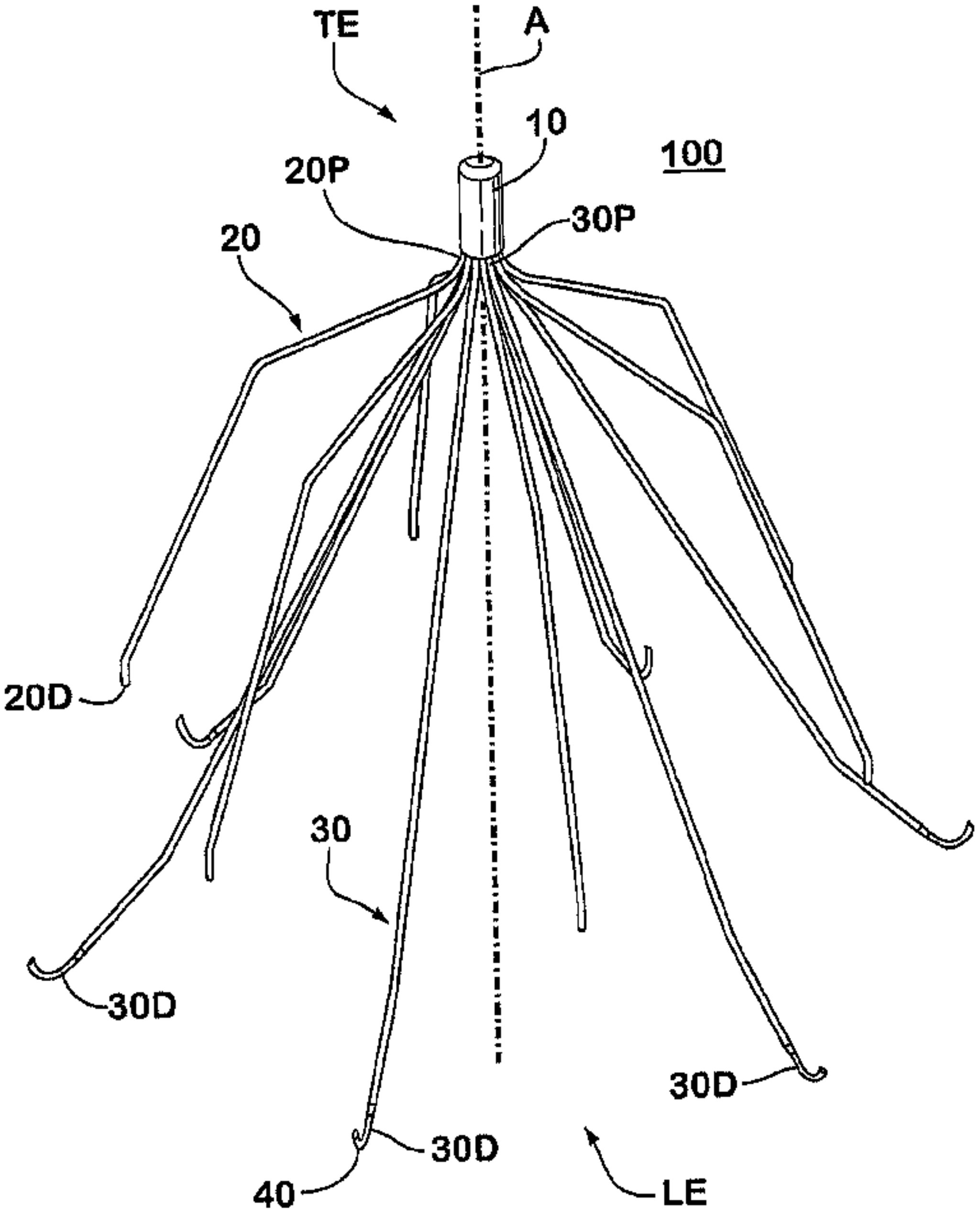


FIG. 14


TE
A
10
100
20P
30P
20
20D
30
30D
30D
40
30D
LE