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(54) MEDICAL DEVICE ANCHOR AND DELIVERY SYSTEM

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(52) **U.S. Cl.** **606/200**

(57) **ABSTRACT**

A method and apparatus for anchoring a medical implant device after the device has been brought to rest at a desired position within a blood vessel or other body passageway. An anchor delivery system is provided which houses one or more uniquely configured expandable anchors which are connected to the medical implant device. The anchors remain housed in a non expanded configuration until after the medical implant device has come to rest in a desired position within the body, and then the anchors are positively propelled through a body wall from a first side to a second side where each anchor expands outwardly from an anchor shaft. In one configuration, the anchors are each formed in the shape of a compressible closed loop which extends outwardly from an anchor shaft and loops back to cross over and extend beyond the anchor shaft. To positively propel the anchors, a drive shaft for the anchor shafts extends back to a triggering unit which, when activated, causes the drive shaft to drive the anchor shafts in a direction which results in propulsion of the anchors through the body wall.

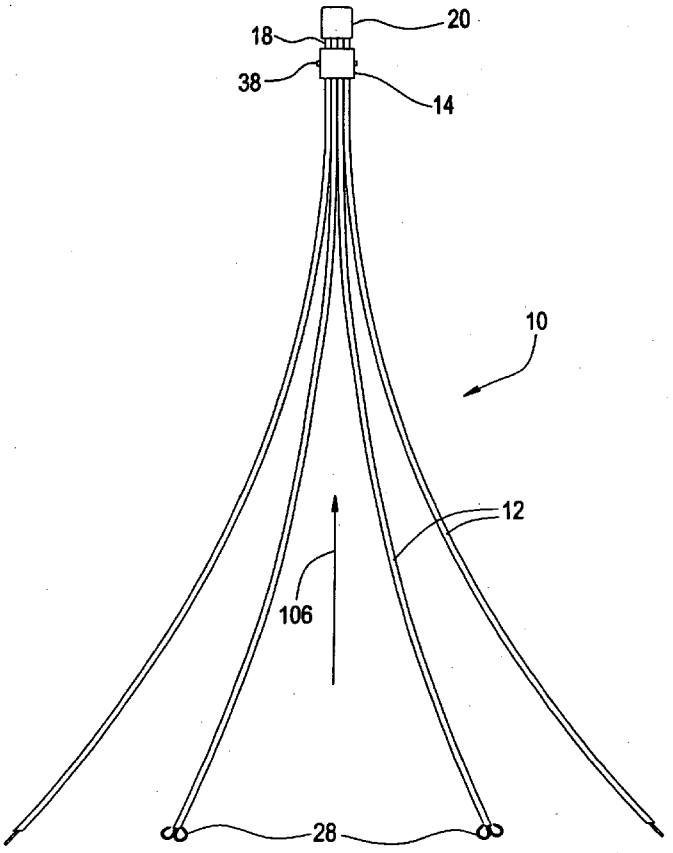

FIG. 1

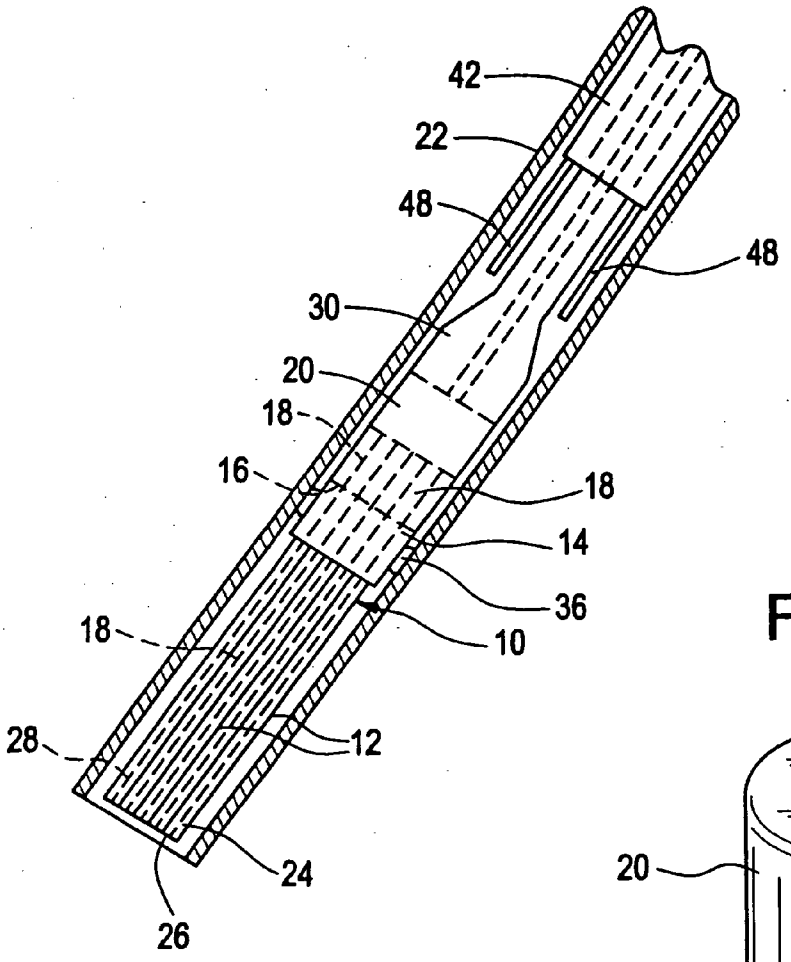
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FIG. 2

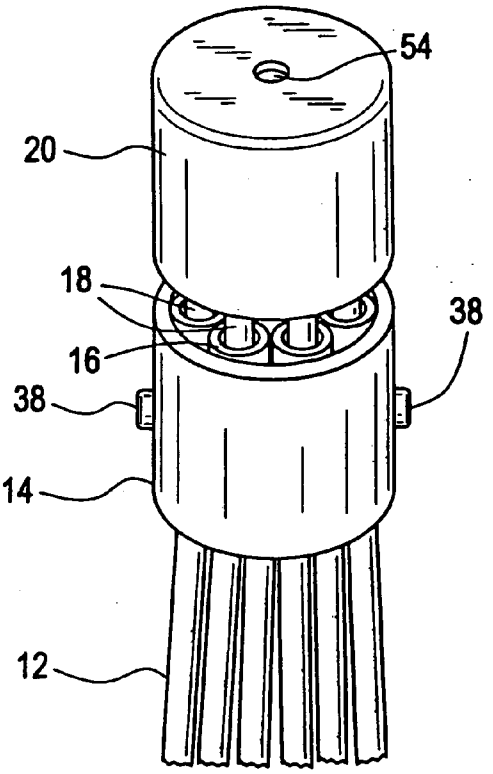
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FIG. 3

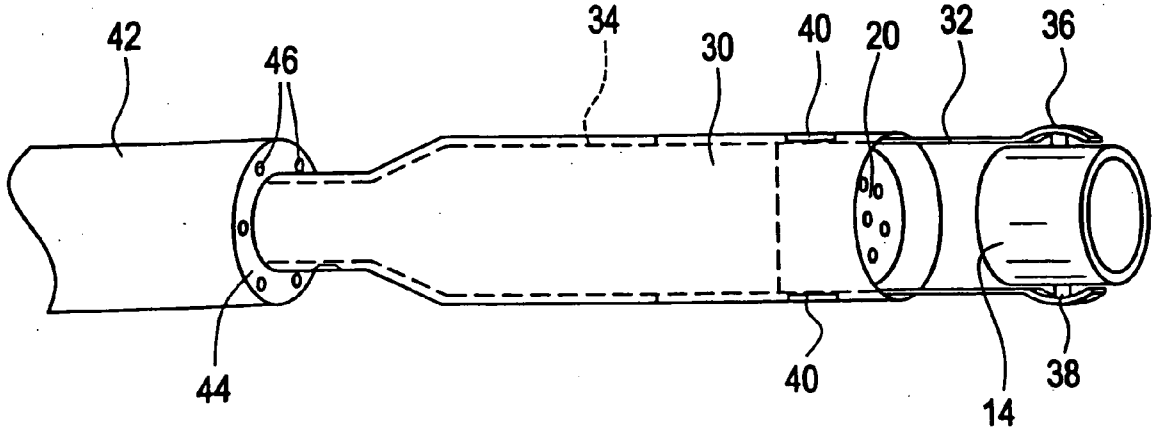
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FIG. 4

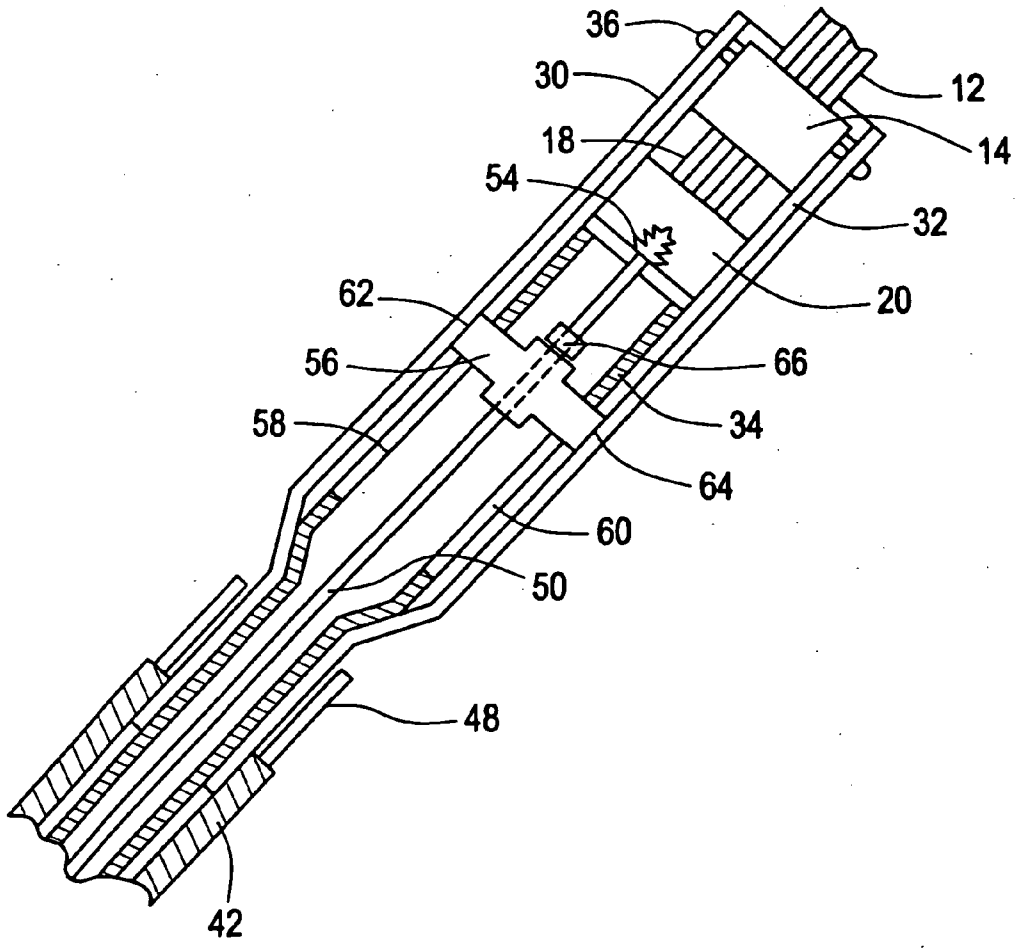
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FIG. 5

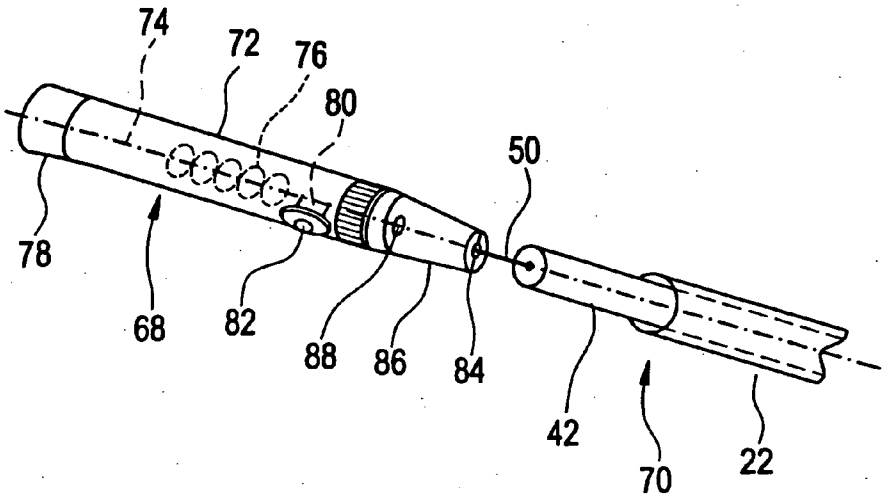

FIG. 7

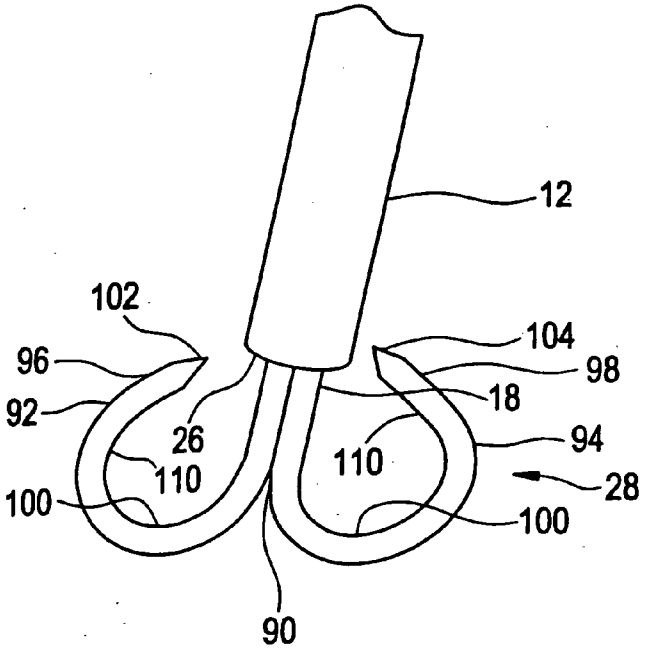

FIG. 8

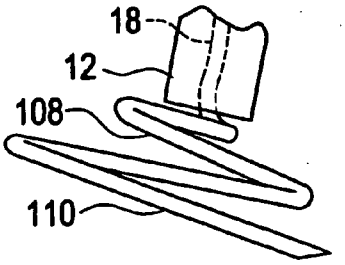

FIG. 6

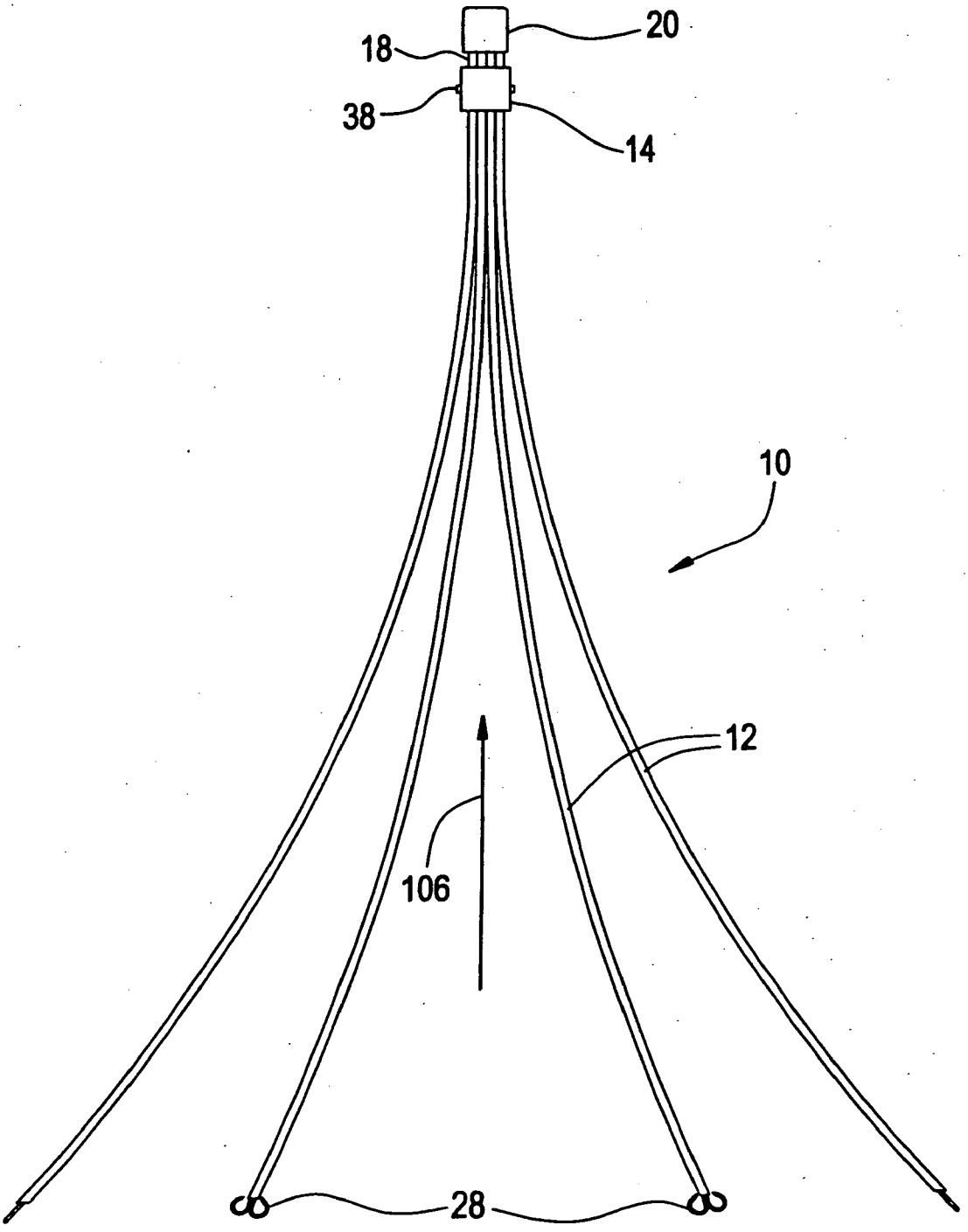

FIG. 10

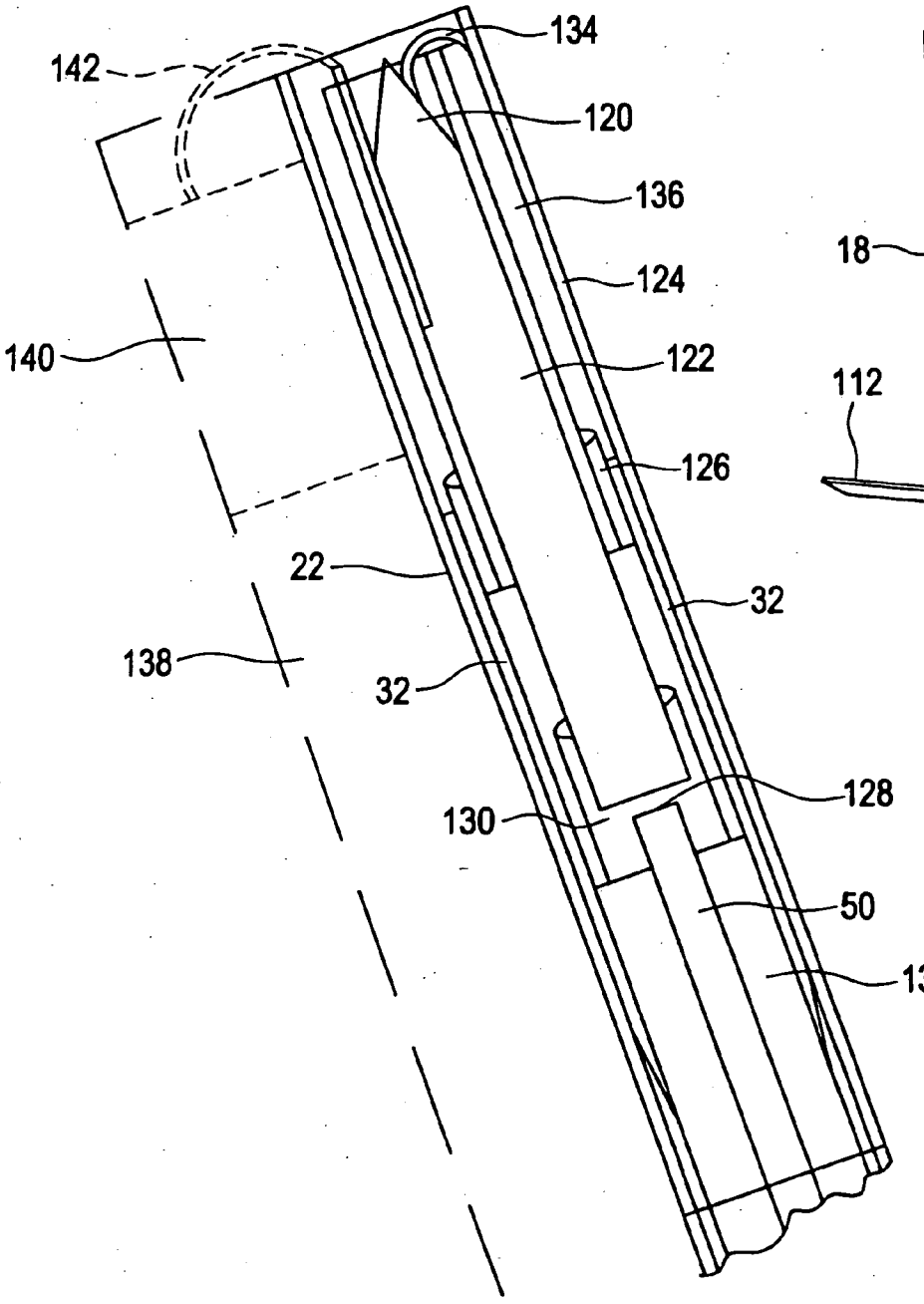
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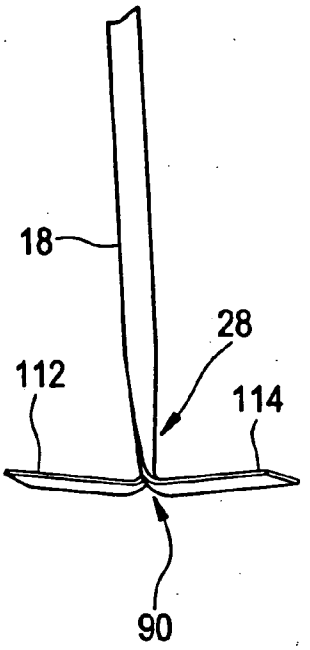
FIG. 9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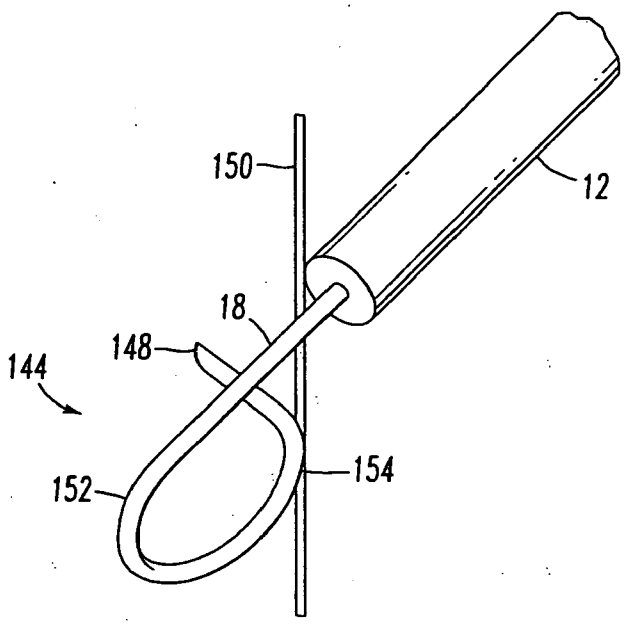

FIG. 11

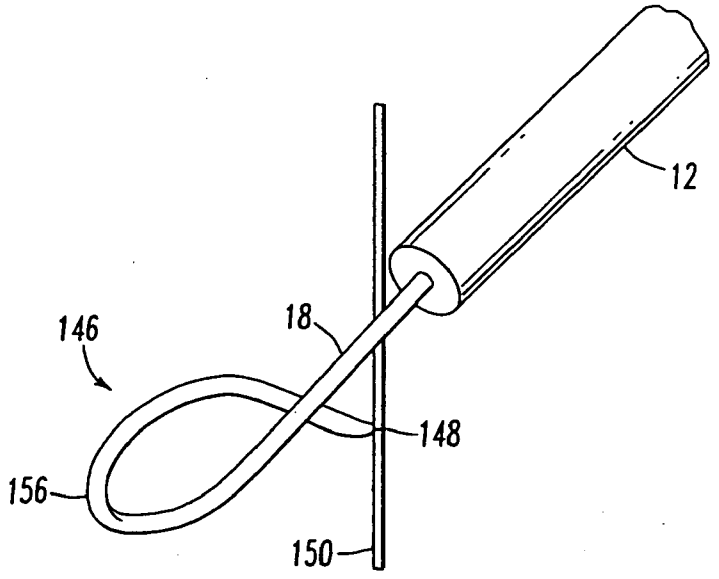

FIG. 12

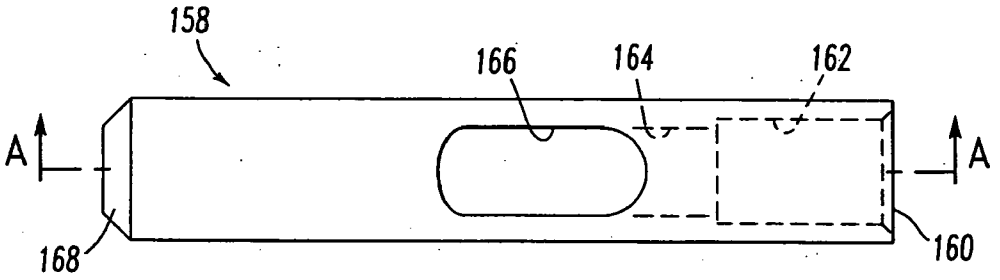

FIG. 13

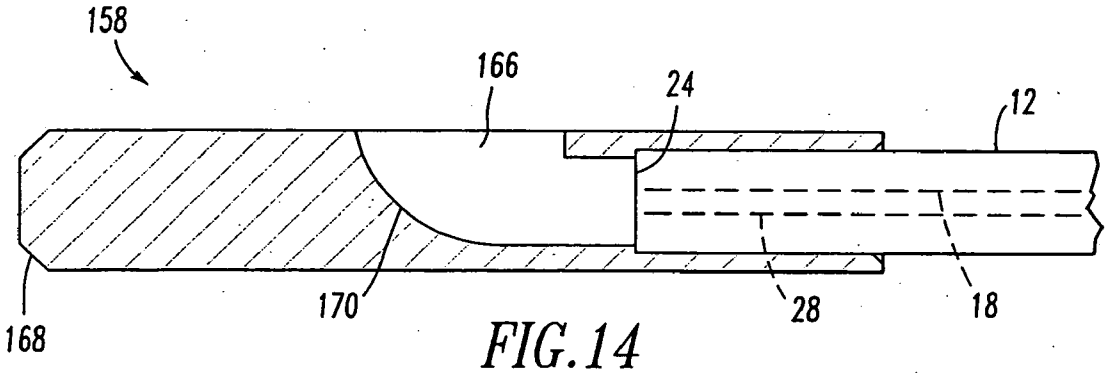

FIG. 14

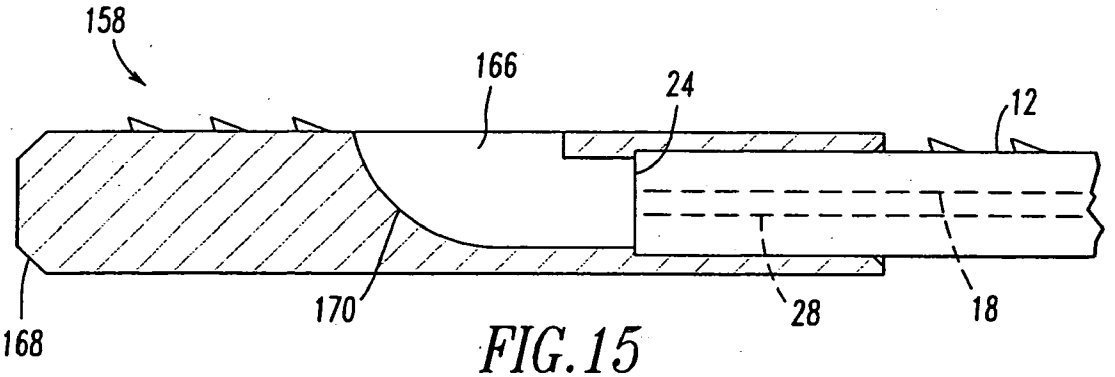

FIG. 15

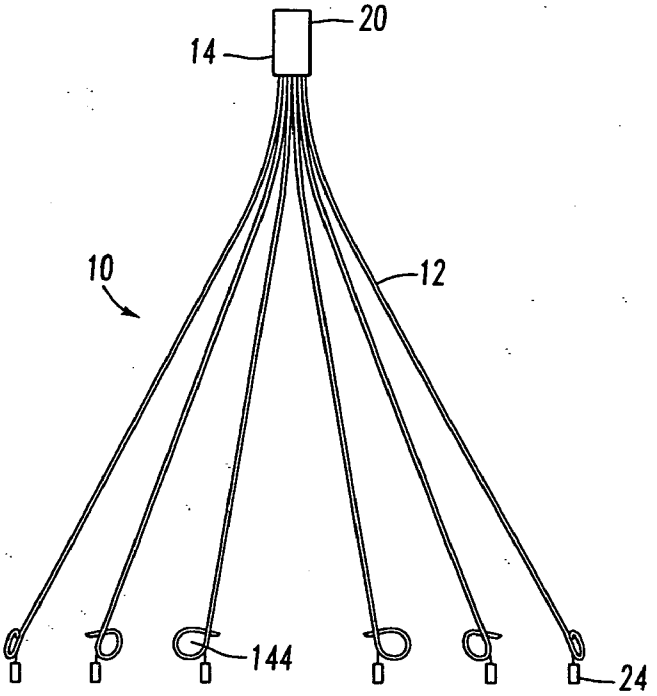

FIG. 16

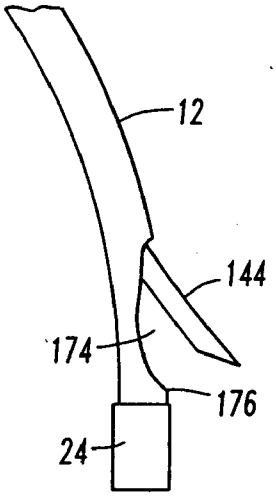

FIG. 17

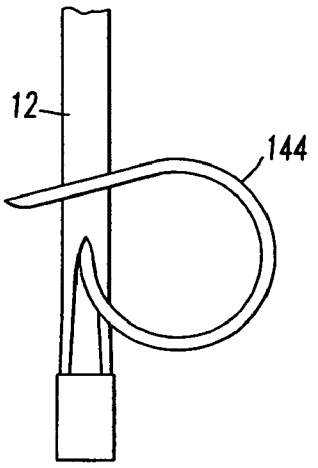

FIG. 18

MEDICAL DEVICE ANCHOR AND DELIVERY SYSTEM

[0001] This application is a Continuation-in-Part application of Ser. No. 10/705,226 filed Nov. 12, 2003.

BACKGROUND OF THE INVENTION

[0002] Recent advances in medical technology have resulted in the development of a variety of medical devices for permanent or temporary implantation in the human body. Effective positioning of such devices can prove to be a very difficult task, and maintaining an implanted device in a desired position for an extended period of time is often more difficult. This is particularly true if the implanted device is to remain only temporarily and is designed to facilitate subsequent removal.

[0003] A number of medical implant devices are designed to collapse for insertion within a catheter or other delivery unit and to expand to a predetermined shape when ejected after delivery. Many of these self expanding devices rely primarily upon the contact between the device and the wall of a body vessel or passageway to maintain the device in position after the delivery unit is removed. Unfortunately, changes in the dimensions of the body vessel or passageway or variations in the flow of blood or other fluids there through can cause the medical implant to migrate and change position.

[0004] It is extremely important that a medical implant device be properly positioned and oriented, and that this position and orientation be maintained. Otherwise, effective performance of such therapeutic devices will not be achieved. It is often very difficult to move such a device into position with the desired orientation, and once this is achieved, it is critical that no further motion occur.

[0005] In an attempt to prevent migration of a medical implant device, rigid hooks are often formed on the device to engage the wall of a body vessel or passageway as the implant device expands into contact with the wall. After a few weeks, the endothelium layer grows over rigid hooks which will not easily bend under the influence of withdrawal pressure, and the medical implant device will be locked in place by the embedded hooks. This may be acceptable for a permanent implant, but rigid hooks are not a viable option if the medical implant device is to be removed after several weeks or months.

[0006] To facilitate removal of a previously implanted medical device by withdrawal of the anchoring hooks from an enveloping endothelium layer without risking substantial damage to the wall of a body vessel or passageway, the hooks have been formed to straighten when subjected to a withdrawal force greater than a maximum migration force. U.S. Pat. Nos. 6,007,558 and 6,258,026 to Ravenscroft, et al show hooks which are formed to bend and straighten in response to a withdrawal force, while U.S. Pat. No. 4,425,908 to Simon, U.S. Pat. No. 4,817,600 to Herms, et al, U.S. Pat. No. 5,108,418 to Lefebvre, U.S. Pat. No. 5,133,733 to Rasmussen, et al, U.S. Pat. No. 5,242,462 to El-Nounou, et al, U.S. Pat. No. 5,370,657 to Irie, U.S. Pat. No. 5,601,595 to Smith, U.S. Pat. No. 5,800,457 to Gelbfish, and U.S. Pat. No. 5,853,420 to Chevillon, et al all disclose expandable medical implant devices; many with anchoring hooks.

[0007] Anchoring hooks, although effective in many instances, are subject to a number of disadvantages which can make it difficult to properly position and maintain the position of a medical implant device. In prior devices, the anchoring hooks are engaged due to the expansion of the device into contact with the wall of a body vessel or passageway, and if the device moves from a desired position during expansion and contact with the wall occurs, the device cannot be easily repositioned. The anchoring function of the hooks is not separable from the expansion of the device.

[0008] In cases where the operation of the hooks is tied to the expansion of a medical implant device, there can be instances where one or more of the hooks fails to properly engage the wall of a body vessel or passageway causing the device to become off center. Sometimes movement of the device longitudinally will engage the errant hooks, but this movement can also alter the position of the device.

[0009] Also, the configuration of a hook which curves in a single direction from a shaft to a pointed end can prove to be a disadvantage. When hooks are used to anchor a medical implant device within a blood vessel, it is important that the hook be oriented to curve in the direction of normal blood flow through the vessel as it engages the vessel wall. Thus when engaged, the hook will extend from the shaft toward the point substantially in the direction of the longitudinal axis of the blood vessel, and will effectively resist migration of the medical implant device in response to pressure thereon from blood flow in the normal direction through the blood vessel. However, there are conditions which can result in a backflow of blood in a blood vessel, and pressure on the device and the anchoring hooks resulting from such backflow can cause the hooks to back out and disengage from the vessel, thus changing the orientation of the device within the blood vessel and causing deleterious changes in the performance of the implant.

[0010] Finally, even if the hooks of an implant device are properly engaged with a vessel wall, there are conditions which result in the subsequent outward expansion of the vessel wall to an extent where the hooks tend to become disengaged.

SUMMARY OF THE INVENTION

[0011] It is a primary object of the present invention to provide a novel and improved method for positioning and anchoring a medical implant device which includes positively propelling one or more anchors through a body wall subsequent to a medical implant device connected to the anchor reaching a desired position and coming to rest.

[0012] Another object of the present invention is to provide a novel and improved medical device anchor and delivery system wherein one or more anchors are positively propelled through a body wall. Once an anchor has passed through the wall, it expands outwardly from at least two opposed sides of an anchor shaft.

[0013] An additional object of the present invention is to provide a novel and improved medical device anchor designed to penetrate a body wall from a first side to a second side and to expand outwardly from at least two opposed sides of an anchor shaft after penetration.

[0014] Another object of the present invention is to provide a novel and improved medical device anchor designed to penetrate the wall of a body vessel from a first side to a

second side and to expand outwardly from an anchor shaft in a unique manner after penetration. The expanded anchor is designed to be loaded in compression against the second wall of the vessel and to change in configuration to increase the anchoring function provided thereby in response to forces applied thereto at an angle to the longitudinal axis of the vessel.

[0015] Yet another object of the present invention is to provide a novel and improved medical device anchor designed to penetrate the wall of a body vessel from a first side to a second side and to expand outwardly from an anchor shaft in a unique manner after penetration. The anchor expands outwardly from the anchor shaft into one or more loops with each loop curving back to cross the anchor shaft. The section of the loop which crosses the anchor shaft is formed to engage the second wall of the vessel and to load the anchor in compression against the second wall of the vessel in response to forces which are applied to a medical device attached to the anchor or which result from expansion of the vessel wall.

[0016] A further object of the present invention is to provide a novel and improved medical device anchor and delivery system wherein one or more anchors are positively propelled through a body wall subsequent to a medical implant device connected to the anchors reaching a desired position and coming to rest. The anchor delivery system facilitates removal and reinsertion of the anchors without requiring that the medical implant device connected thereto be compressed and/or removed.

[0017] Yet another object of the present invention is to provide a novel and improved anchor and anchor delivery system for a medical implant device to anchor the device in position within a blood vessel or other body passageway. Once the medical implant device has been positioned and expanded into contact with the wall of the blood vessel or body passageway, the anchor delivery system then positively propels one or more anchors through the vessel or passageway wall where the anchors expand outwardly on opposite sides of an anchor shaft. The anchor delivery system permits the anchors to be withdrawn and then reinserted through the wall without the necessity to collapse the medical implant device.

[0018] A further object of the present invention is to provide a novel and improved anchor and anchor delivery system for a medical implant device to anchor the device in position within a blood vessel or other body passageway while facilitating the subsequent withdrawal of the device. The anchor delivery system positively propels one or more anchors through the wall of a blood vessel or body passageway once the medical implant device has expanded into contact with the wall, and the anchors then expand outwardly from opposite sides of an anchor shaft. The anchors are formed to contract back toward the longitudinal axis of the anchor shaft in response to a predetermined force to permit withdrawal through the wall.

[0019] A still further object of the present invention is to provide a novel and improved anchor and anchor delivery system for a blood clot filter where the delivery system includes elongate, tubular filter legs which house the anchors. Once the filter legs are ejected from a catheter or delivery tube and expand into contact with the blood vessel wall, the anchor delivery system positively propels the anchors outwardly from the filter legs and through the blood vessel wall from a first side to a second side where the anchors expand outwardly from an anchor shaft against the second side of the wall. Each anchor is formed to contract back toward the longitudinal axis of its anchor shaft in response to a predetermined force to permit withdrawal through the wall, and this permits the anchors to be withdrawn back into the filter legs and then again propelled through the blood vessel wall without collapsing the filter legs.

[0020] Yet a further object of the present invention is to provide a novel and improved anchor delivery system for a blood clot filter where the delivery system includes elongate, tubular filter legs which house the anchors and which expand into contact with a blood vessel wall. A side opening is formed in the portion of the filter leg which will contact the blood vessel wall, and the filter leg is designed to facilitate ejection of the anchor through the side opening transverse to the filter leg. Once the filter legs expand into contact with the blood vessel wall, the anchor delivery system positively propels the anchors laterally outward from the side openings in the filter legs and through the blood vessel wall from a first side to a second side where the anchors expand outwardly from an anchor shaft against the second side of the blood vessel wall.

[0021] These and other objects of the present invention are achieved by providing an anchor delivery system which houses one or more uniquely configured anchors which are connected to a medical implant device. The anchors remain housed until after the medical implant device has come to rest in a desired position within a body, and then the anchors are positively propelled through a body wall from a first side to a second side where each anchor expands from a single shaft configuration. To propel the anchors, a drive shaft extends from an anchor support sleeve back to a triggering unit which, when activated, causes the drive shaft to move the anchor support sleeve in a direction to propel the anchors through the body wall. The triggering unit may be spring powered or solenoid powered.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] **FIG. 1** is a sectional view showing a blood clot filter with anchors formed in accordance with the present invention mounted within a catheter;

[0023] **FIG. 2** is a perspective view showing the anchor support hub and leg retention sleeve of **FIG. 1**;

[0024] **FIG. 3** is a perspective view showing the locking sleeve for the leg retention sleeve of **FIG. 2**;

[0025] **FIG. 4** is a sectional view showing the operating mechanism for the locking sleeve and anchor support hub of **FIG. 1**;

[0026] **FIG. 5** is a perspective view showing a spring powered triggering unit at the proximal end of the catheter of **FIG. 1** for propelling the anchor support hub;

[0027] **FIG. 6** is a perspective view of the deployed blood clot filter of **FIG. 1**;

[0028] **FIG. 7** is a perspective view of a deployed anchor for the blood clot filter of **FIG. 6**;

[0029] **FIG. 8** is a perspective view of a second embodiment of a deployed anchor of the present invention;

[0030] **FIG. 9** is a perspective view of a third embodiment of a deployed anchor of the present invention;

[0031] **FIG. 10** is a sectional view of a single anchor and anchor delivery system of the present invention;

[0032] **FIG. 11** is a perspective view of a fourth embodiment of a deployed anchor of the present invention which deploys to form a closed loop having a wall engaging section which crosses over and extends beyond the anchor shaft;

[0033] **FIG. 12** is a perspective view of a fifth embodiment of a deployed anchor of the present invention which deploys to form a closed loop having a wall engaging section which crosses under and extends beyond the anchor shaft;

[0034] **FIG. 13** is a view in side elevation of an anchor guide boot which is secured to the end of an anchor containing blood clot filter leg,

[0035] **FIG. 14** is a sectional view of the anchor guide boot of **FIG. 13**,

[0036] **FIG. 15** is a sectional view of a modification of the anchor guide boot of **FIG. 14**.

[0037] **FIG. 16** is a perspective view of a deployed blood clot modified to eject anchors from the side of the filter legs above the distal ends of the legs with the anchors deployed,

[0038] **FIG. 17** is a view in front elevation of an end section of a filter leg of the filter of **FIG. 16** with an anchor partially deployed, and

[0039] **FIG. 18** is a view in front elevation of an end section of a filter leg of the filter of **FIG. 16** with an anchor fully deployed.

DETAILED DESCRIPTION

[0040] Referring to **FIGS. 1-2**, a blood clot filter which includes anchors in accordance with the present invention is illustrated generally at **10**. This filter, shown for illustration as a vena cava filter, is formed with a plurality of elongate legs **12** which are secured to, and extend outwardly from a leg retention sleeve **14**. The elongate legs are formed by small, open ended tubes each having a first open end **16** which opens at the leg retention sleeve. A plurality of long anchor shafts **18** are attached at a distal end to an anchor support hub **20** which is spaced from the leg retention sleeve when the vena cava filter is collapsed within a catheter or delivery tube **22**. Each shaft **18** extends from the anchor support hub **20** into the first open end **16** of a tubular leg **12** and through the leg to a distal end **24** at a point adjacent to a second open end **26** of the tubular leg. An anchor **28** is formed at the distal end of each shaft **18** in a manner to be described.

[0041] The elongate legs **12** and the long anchor shafts **18** are formed of a material which will permit them to be compressed toward the longitudinal axis of the filter **10** for delivery by a catheter **22**. Once the filter is ejected from the catheter, the legs **12** and the shafts **18** are designed to expand outwardly from the filter longitudinal axis as shown in **FIG. 6** to bring the legs into contact with the wall of a blood vessel. Although spring metal and suitable plastics can be used to form the legs **12** and/or the shafts **18**, it is preferable to form the anchor shafts **18** and in most cases the legs **12** of a suitable shape memory material. If a temperature responsive shape memory material such as nitinol is used, transition between the martensitic and austenitic states of the material can be achieved by temperature transitions relative to a transition temperature. In the martensitic state, the material softens, thereby permitting a filter formed thereof to be compressed and loaded into a catheter. If the transition temperature of the material is set at, or near to normal body temperature, then the filter legs will pass to the austenitic state when the filter is ejected from the catheter and expand to regain a memorized shape.

[0042] For delivery through the catheter **22**, the leg retention sleeve **14** is locked to the anchor support hub **20** by a locking sleeve **30** which surrounds both the anchor support hub and the leg retention sleeve when in the locking position as shown in **FIG. 1**. In the unlocked position, the locking sleeve is moved longitudinally back away from the leg retention sleeve as shown in **FIG. 3**. Two spring arms **32** are connected at one end to a housing **34** behind the anchor support hub and extend outwardly over opposite sides of the leg retention sleeve. The free end of each of the spring arms is curved to form an arcuate latch member **36** which overlies and, in the locking position of **FIG. 1**, engages a locking projection **38** formed on the leg retention sleeve. When the locking sleeve **30** moves toward the locking position over the leg retention sleeve **14**, it forces the spring arms **32** and **34** together and the arcuate latch members engage the locking projections. As the locking sleeve reaches the full locking position of **FIG. 1**, the arcuate latch members slide into slots **40** in the locking sleeve and the leg retention sleeve is positively locked to the anchor support hub. However, as the locking sleeve is moved longitudinally away from the leg retention sleeve, the arcuate configuration of the latch members **36** permits them to slip out of the slots **40**, and as the locking sleeve moves further, the spring arms **32** move outwardly causing the arcuate latch members to disengage the locking projections **38**.

[0043] The locking sleeve **30** is mounted for movement toward and away from a centering shaft **42** which extends from a distal end **44** adjacent to the vena cava filter **10** back to the entry end of the catheter **22**. The distal end of the centering shaft is formed with a plurality of spaced lumens **46**, each of which mounts one of a plurality of centering arms **48**. The centering shaft moves these centering arms out of the catheter **22** behind the vena cava filter, and these centering arms then expand outwardly to engage the vessel wall and center the leading end of the filter. These centering arms can be formed of spring metal or plastic, but are preferably formed of shape memory material such as nitinol.

[0044] To control the positioning of the vena cava filter **10** and subsequent ejection of the anchors **28** from the second open ends of the legs **12**, an elongate drive shaft **50** extends from the entry or proximal end **52** of the catheter **22** through the catheter to a releasable connection **54** with the anchor support hub **20**. This releasable connection can be any suitable connection which facilitates release of the drive shaft from the anchor support hub by manipulation of the drive shaft at the proximal end of the catheter such as a threaded connector as shown, a hook and eye connector, engaging hook connectors, and known twist engagement and release connectors. This drive shaft passes through the centering shaft **42** and is both rotationally and longitudinally movable relative thereto.

[0045] As shown in **FIG. 4**, the drive shaft passes through and is both rotationally and longitudinally movable relative

to a locking sleeve operator **56** which passes through slots **58** and **60** in the housing **34**. The locking sleeve operator is secured at **62** and **64** to the locking sleeve **30** and operates to move the locking sleeve away from the leg retention sleeve **14** as the locking sleeve operator moves away from the leg retention sleeve in the slots **58** and **60**. The drive shaft operates to move the locking sleeve from the locked position by means of a stop **66** secured to the drive shaft and positioned to engage the locking sleeve operator.

[**0046**] When the catheter **22** reaches a desired position within a blood vessel, the vena cava filter **10** and centering arms **48** are exposed by either ejecting them from the catheter or drawing the catheter back from around them. Now the elongate legs **12** and centering arms **48** will expand outwardly into engagement with the vessel wall. However, the anchors **28** will remain enclosed within the elongate legs, and this permits the vena cava filter to be moved relative to the blood vessel after expansion of the elongate legs until an exact position is attained. If a substantial position change is required, the centering arms and vena cava filter can be drawn back into the catheter and subsequently redeployed in a new position.

[**0047**] With the vena cava filter in the desired position within a blood vessel and the elongate legs **12** engaging the vessel wall, the anchors **28** are now positively ejected out from the second open ends **26** of the elongate legs so as to penetrate through the vessel wall. To achieve this positive ejection of the anchors subsequent to engagement of the elongate legs with the vessel wall with sufficient force to result in penetration of the vessel wall, the drive shaft **50** is connected to a triggering unit **68** at the proximal or entry end **70** of the catheter **22**. This triggering unit can be formed by a number of known units capable of imparting a longitudinal force to the drive shaft. An electrically powered solenoid unit can be used for this purpose as well as a number of spring powered units. In **FIG. 5**, the triggering unit is formed by a conventional ballistic-type lancer of the type commonly used to cause a needle to puncture a patient's skin to provide a blood sample. Such lancers include a hollow body **72** which contains a plunger **74** capable of moving axially back and forth within the body. The plunger is surrounded by a coil spring **76** which becomes compressed when the plunger is pulled back and armed by an end knob **78**. The armed plunger is held in place by a trigger **80** which is activated to release the plunger by a button **82**. When the plunger is released, the coil spring **76** propels the plunger toward an opening **84** in a nose cap **86** attached to the hollow body. For normal use of the ballistic type lancer, a needle is secured to the end **88** of the plunger and is propelled by the released plunger out through the opening **84** and into the skin of a patient. In **FIG. 5**, the drive shaft **50** is secured to the end **88** of the plunger, and when the armed plunger is released, the drive shaft is propelled longitudinally to drive the anchor support hub **20** toward the leg retention sleeve **14**. This causes the long shafts **18** to move longitudinally through the elongate legs **12** to propel the anchors out and through the vessel wall. **FIG. 6** illustrates an expanded vena cava filter **10** with the anchors **28** in the configuration that they would assume after passing through the vessel wall. The structure and operation of these anchors will be subsequently described.

[**0048**] A significant advantage of the vena cava filter **10** is that it can be repositioned even after the anchors are in place without the necessity to withdraw the complete filter back into the catheter **22**. So long as the elongate legs are in contact with the vessel wall, the anchors **28** can be withdrawn from the vessel wall and back into the elongate legs by causing the drive shaft **50** to move the anchor support hub **20** away from the leg retention sleeve **14**. Now the vena cava filter can be repositioned, the plunger **74** of the triggering unit **68** can be rearmed, and the anchors can again be ejected to pierce the vessel wall.

[**0049**] Once the vena cava filter **10** is properly positioned and anchored within a blood vessel, the drive shaft **50** is disconnected from the anchor support hub **20** and is pulled away from the anchor support hub causing the stop **66** to engage and move the locking sleeve operator **56** away from the anchor support hub. This results in movement of the locking sleeve **30** away from the leg retention sleeve **14** so that the spring arms **32** spring outwardly and the latch members **36** disengage from the locking projections **38**. Now the centering shaft **42**, locking sleeve **30**, drive shaft **50** and housing **34** may be drawn back through the catheter **22** leaving the vena cava filter in place within the blood vessel.

[**0050**] To subsequently remove a previously anchored vena cava filter, standard body retrieval devices which engage the filter body may be used. For example, a hook to be engaged by a retrieval device can be attached to the anchor support hub **20**.

[**0051**] The anchors **28** are formed at the proximal ends of the long anchor shafts **18**, and within the elongate legs **12** the anchors assume the same configuration as the shafts with which they are integrally formed. The shafts conform in configuration to the internal configuration of the elongate legs so as to easily move longitudinally within the elongate legs, and usually the shafts will be cylindrical with a pointed end which forms the leading end of the anchor. An enlarged view of the anchor of **FIG. 6** is shown in **FIG. 7**.

[**0052**] Referring to **FIG. 7**, the tubular anchor shaft **18** is split down the center at **90** to form the opposed arms **92** and **94** of the anchor. The inner surfaces **96** and **98** of each of the arms is flat while the remaining surface **100** of each arm is arcuate, so that when the inner surfaces of the arms are contacting, a straight tubular end section is formed on the end of each long shaft **18**. The pointed end of each long shaft forms the pointed ends **102** and **104** on the arms **92** and **94** of the anchor.

[**0053**] The expanded shape memory configuration of the anchors **28** is shown in **FIGS. 6 and 7**. Each anchor with the inner surfaces **96** and **98** in contact is ejected from an elongate leg **12** in a straight configuration when the anchor support hub **20** is driven toward the leg retention sleeve **14**. The pointed lead end of each anchor will pierce the wall of a blood vessel so that the entire anchor passes through the vessel wall, at which point the anchor expands to its shape memory configuration shown in **FIG. 7**. Now the end **26** of the elongate leg engages the inner surface of the blood vessel wall while the pointed ends **102** and **104** of the arms **92** and **94** engage the outer surface of the blood vessel wall. It is important to note that portions of the expanded anchor, in this case the arms **92** and **94**, extend outwardly on opposite sides of the shaft **18** so that forces in either direction in the plane of the anchor arms will not dislodge the anchor in the manner which can occur with a single hook which extends outwardly in only one direction from a support shaft. To

provide additional protection from accidental dislodgement, the anchors **28** are oriented as shown in **FIG. 7** so that the opposed arms **92** and **94** of the anchor expand transversely to the longitudinal direction **106** of blood flow through the filter **10**. Thus the forces created by direct or reverse blood flow cannot dislodge the anchor, but since the anchor arms are each formed from half of a shaft **18** of a very small diameter, a withdrawal force along the longitudinal axis of the shaft will permit the anchor arms to come together to facilitate anchor withdrawal from the vessel wall.

[**0054**] It is important to note that the anchor arms **92** and **94** curve outwardly and back toward the shaft **18** to engage the outside surface of the vessel wall. This causes the anchor to be loaded in compression against the vessel wall when forces normal to the longitudinal axis of the vessel are applied to a medical device attached to the anchor. This compression aspect greatly enhances the anchoring function provided by the anchor and facilitates the effective use of very small, fine anchor components.

[**0055**] The anchors **28** may take a number of forms so long as the anchor expands from a straight configuration from within an elongate leg **12** to a shape memory configuration where the anchor extends outwardly on at least two opposite sides of the shaft **18**. In **FIG. 8**, the anchor **28** expands to a spiral configuration so as to extend completely around the shaft **18**. Here the shaft is not split as shown in **FIG. 7**, but instead the intact end of the shaft is used to form the spiral **108**. In all cases, first end of the anchor to emerge from an elongate leg **12** is a straight section **110** bearing the anchor point, and this section passes through a blood vessel wall before following sections which will form curves emerge. Both the anchors of **FIGS. 7 and 8** tend to flatten by spring action against the vessel wall after expanding.

[**0056**] To form the anchor **28** of **FIG. 9**, the shaft **18** is flattened at the end and split at **90** to form two opposed, flat arms **112** and **114** which expand outwardly on opposite sides of the shaft. These arms emerge from the elongate leg **12** as a straight section which passes through the vessel wall and then splits and bends outwardly at **116** and **118** to form the arms. These arms lie against the outer surface of the vessel wall and in a vena cava filter, are oriented transverse to the longitudinal direction of blood flow through the filter.

[**0057**] For some medical applications, a need has arisen for a single anchor to tether a device within a body vessel or to a body wall. An apparatus similar to that previously described with reference to the multiple anchor vena cava filter **10** can be employed to deploy the single anchor **120** of **FIG. 10**. The single anchor **120** is formed at the distal end of an anchor shaft **122** mounted in an elongate tube **124**, Both the shaft **122** and the tube **124** are formed of shape memory material as described relative to the elongate legs **12** and long shafts **18**, but are normally much shorter in length than the elongate legs and shafts **18**. A tube retention sleeve **126** retains the single tube **124** in the same manner that the leg retention sleeve **14** operates to retain the elongate legs **12**, and this tube retention sleeve is engaged by a locking sleeve (not shown) and spring arms **32** operative in the manner previously described. A drive shaft **50** is connected at the entry end of the catheter **22** to a triggering unit **68**, and is also connected to a releasable connection **128** similar to the releasable connection **54**. This releasable connection is firmed in a shaft support hub **130** normally spaced from the tube retention sleeve **126** which is connected to the proximal end of the anchor shaft.

[**0058**] The drive shaft **50** is movable in a control shaft **132** similar to the centering shaft **42** which operates to move the shaft support hub and tube retention sleeve longitudinally to expel the tube **124** containing the anchor **120** from the catheter **22**. The tube **124** will now assume a predetermined shape to position the anchor relative to a body wall which will receive the anchor. Now the triggering unit **68** can be operated to cause the drive shaft **50** to move the shaft support hub **130** toward the tube retention sleeve **126** to drive the anchor **120** through the body wall. The anchor **120** is formed of shape memory material and can take the form and operate in the manner of any of the anchors previously described. Once the anchor is delivered, the spring arms **32** can be operated to release the tube retention sleeve **126**, and the drive shaft can be released from the releasable connection **128** so that the drive and control shafts, and in some cases the catheter, can be withdrawn. If the purpose of the anchor is to anchor the catheter in position, then a tether **134** is provided between the catheter and the anchor, and the catheter will not be withdrawn with the drive and control shafts.

[**0059**] In some instances, the catheter **22** may be a dual lumen catheter having a first lumen **136** containing the described anchor mechanism and a second lumen **138** containing an in implantable medical device **140** to be anchored by the anchor **120**. In this case, a tether **142** is connected between the anchor and the implant able medical device, and once the anchor is in place, the implantable medical device is ejected from the catheter.

[**0060**] When it is possible to use the catheter to properly position the anchor **120** relative to a body wall, the tube **124** and tube retention sleeve **126** can be eliminated and replaced by the catheter lumen. Now the drive shaft **50** will drive the shaft support hub **130** longitudinally to drive the anchor from the catheter lumen and through the body wall.

[**0061**] **FIGS. 11 and 12** show anchors **144** and **146** respectively which each form a single, closed loop in the expanded shape memory configuration. Each of the anchors **144** or **146** is ejected from an elongate leg **12** in a straight configuration coextensive with the long anchor shaft **18** when the anchor support hub **20** is driven toward the leg retention sleeve **14**. The end of each anchor, which may be pointed as indicated at **148**, will pierce the wall **150** of the vessel containing the vena cava filter **10** or other medical implant device to be anchored, so that the entire anchor passes through and expands against the outer surface of the vessel. In its shape memory expanded configuration, the anchor **144** extends arcuately outwardly from the anchor shaft and loops back to cross over and extend beyond the anchor shaft to form a single closed loop **152**. The loop **152** engages the outer surface of the vessel wall **150** at **154** and is loaded in compression against the vessel wall; a compression which increases in response to forces applied in any direction which tend to force the loop **152** further against the vessel wall. As these forces increase, the loop **152** changes configuration and decreases in size becoming more rigid as a greater portion of the loop is forced across the anchor shaft **18**, thereby increasing the anchoring force of the anchor.

[**0062**] Unlike the anchor **144** which is oriented to be confined in the angular space between the anchor shaft **18**

and the vessel wall **150**, the anchor **146** is oriented to be outside this angular space. This anchor in its shape memory expanded configuration extends arcuately outwardly from the anchor shaft and loops back to cross under and extend beyond the anchor shaft to form a single closed loop **156** which is loaded in compression against the vessel wall. However, due to the orientation and configuration of the anchor **146**, as forces on the anchor increase, the loop straightens rather than decreasing in size and may be withdrawn with less force than that required to withdraw the anchor **144**.

[**0063**] Both the anchors **144** and **146** can be configured to provide a double looped anchor by splitting the shaft **18** and forming double, opposed closed loops similar to the open loops formed by the arms **92** and **94** of **FIG. 7**. However both the double closed loops of the modified anchors **144** and **146** would extend arcuately back over or under the anchor shaft in the manner shown by **FIG. 11** or **12**.

[**0064**] It may be desirable to insure that the distal end **24** of an anchor containing filter leg **12** cannot follow an ejected anchor through the sidewall of a blood vessel once the anchor is deployed. This can be accomplished in accordance with this invention by forming a side opening in the portion of the filter leg which will contact the vessel wall with this side opening being spaced above the distal end of the filter leg. The anchor is then ejected through this side opening laterally of the filter leg once the filter leg has expanded into contact with the vessel wall. The anchor will now pass through the vessel wall at a point above the distal end of the filter leg thereby positively precluding the distal end of the filter leg from following the anchor through the vessel wall.

[**0065**] It has been found to be advantageous to attach a separate anchor guiding boot **158** of the type shown in **FIGS. 13, 14** and **15** to the distal end **24** of each anchor containing filter leg. The anchor guiding boot has an open end **160** which opens into an internal seat **162** for the distal end of the filter leg. The end of the filter leg may be secured within the seat **162** by any known means such as by a friction fit, welding, heat expansion or bonding. An internal passage **164** connects the seat **162** to a side opening **166** formed in the anchor guiding boot, and this side opening is spaced from the closed end **168** of the anchor guiding boot. The internal passage is closed by a curved, guidewall **170** which curves upwardly from the lower end of the opening **166** to the opposite side of the internal passage.

[**0066**] When the triggering unit **68** is activated, each of the long anchor shafts **18** move an anchor **28** toward the closed end **168** of an anchor guiding boot **158** and into engagement with the curved, guidewall **170** which closes the internal passage **164**. The anchor is then guided along the curved, guidewall. causing the shaft **18** to bend as the anchor is ejected out through the side opening **166** and laterally through the wall of the blood vessel. The anchor guiding boot **158** may be formed of tantalum to provide high feasibility under fluoroscopy.

[**0067**] To prevent longitudinal movement of a filter leg **12** relative to the blood vessel caused by the force applied to the curved, guidewall **170** by the ejecting anchor **28**, barbs **172** may be formed on either the anchor guiding boot **158**, the filter leg **12** or both. These barbs engage the blood vessel wall when the filter leg contacts the vessel wall, and are inclined to penetrate and prevent longitudinal movement of the filter leg toward the closed end **168** of the anchor guiding boot.

[**0068**] To eliminate the need for the anchor guiding boot **158**, a side opening **174** to facilitate lateral anchor ejection when the triggering unit **68** is activated can be formed directly in a filter leg **12** and spaced above the distal end **24** thereof as shown in **FIGS. 16-18**. The tubular filter leg is closed between the lower end of the side opening **174** and the distal end of the filter leg so that the anchor will be ejected laterally of the filter leg through the side opening. This closure may be formed by a curved wall **176** which curves upwardly from the lower end of the side opening across the tubular interior of the filter leg. The filter **10** of **FIG. 16** is shown in the expanded configuration with the anchors **144** deployed laterally through the side openings **174**. **FIG. 17** shows this anchor partially deployed, while **FIG. 18** shows this anchor fully deployed.

We claim:

1. A medical device anchor for penetration through a body wall from a first side to a second side thereof and expansion against said second side comprising:

an anchor shaft having a proximal end and a distal end,

an expandable anchor at the distal end of said anchor shaft having one or more anchor sections, said expandable anchor having a first collapsed configuration wherein said anchor is substantially coextensive with said anchor shaft and a second expanded configuration wherein said one or more anchor sections extend arcuately outwardly from said anchor shaft and loop back to cross and extend beyond said anchor shaft to form a closed loop.

2. The medical device anchor of claim 1 wherein said expandable anchor includes a pointed lead end.

3. The medical device anchor of claim 1 wherein said one or more anchor sections are configured to extend outwardly from said anchor shaft and loop back to cross over said anchor shaft in the second expanded configuration of said expandable anchor.

4. The medical device anchor of claim 1 wherein said one or more anchor sections are configured to extend outwardly from said anchor shaft and loop back to cross under said anchor shaft in the second expanded configuration of said expandable anchor.

5. The medical device anchor of claim 3 wherein said one or more anchor sections compress against said body wall and change configuration to form a smaller closed loop in response to forces which draw said one or more anchor sections against said body wall in the second expanded configuration of said expandable anchor.

6. The medical device anchor of claim 2 wherein said expandable anchor is formed of shape memory material which is compliable and compressible in a first state and which is self-expandable in a second state to a substantially rigid, predetermined spiral configuration.

7. The medical device anchor of claim 1 wherein the proximal end of said anchor shaft is connected to a shaft support hub, said shaft support hub having a connector for receiving a drive shaft.

8. A medical device anchor and delivery system for propelling an anchor through a body wall from a first side to a second side where said anchor expands against said second side comprising:

an anchor shaft having a proximal end and a distal end,

an expandable anchor at the distal end of said anchor shaft having one or more anchor sections, said expandable anchor having a first collapsed configuration wherein said anchor is substantially coextensive with said anchor shaft and a second expanded configuration wherein said one or more anchor sections extend arcuately outwardly from said anchor shaft and loop back to cross and extend beyond said anchor shaft to form one or more closed loops,

a shaft support hub connected to the proximal end of said anchor shaft,

an elongate tube having an entry end and an exit end, said tube containing said anchor shaft with said expandable anchor in said collapsed configuration adjacent to said exit end, and

a drive shaft having a first end in engagement with said shaft support hub and operative when propelled to cause said shaft support hub to move said anchor shaft longitudinally of said elongate tube to propel said expandable anchor outwardly from the exit end of said tube.

9. The medical device anchor and delivery system of claim 8 wherein said drive shaft includes a second end opposite to said first end, said second end being connected to a propulsion unit operative to propel said drive shaft.

10. The medical device anchor and delivery system of claim 9 wherein the entry end of said elongate tube is connected to a tube retention sleeve, said anchor shaft extending outwardly from the entry end of said elongate tube to said shaft support hub spaced from said tube retention sleeve when said expandable anchor is in said collapsed configuration within said elongate tube,

said drive shaft operating when propelled to move said shaft support hub toward said tube retention sleeve.

11. The medical device anchor and delivery system of claim 10 wherein said expandable anchor includes a pointed lead end.

12. The medical device anchor and delivery system of claim 11 wherein said one or more anchor sections curve outwardly from said anchor shaft and back to cross over said anchor shaft in the second expanded configuration of said expandable anchor.

13. The medical device anchor and delivery system of claim 11 wherein said one or more anchor sections curve outwardly from the anchor shaft and back to cross under said anchor shaft in the second expanded configuration of said expandable anchor.

14. The medical device anchor and delivery system of claim 11 wherein said expandable anchor is formed of thermal shape memory material having a temperature transformation level where at temperatures below said temperature transformation level said shape memory material is relatively pliable and compressible and at temperatures at least at or above said temperature transformation level said shape memory material is self-expandable to a substantially rigid predetermined configuration.

15. A blood clot filter with an anchor delivery system for propelling one or more anchors through the wall of a blood vessel from a first inner side to a second outer side, the blood clot filter having a central longitudinal axis and being collapsible to a collapsed configuration toward said longitudinal axis and expandable in an expanded configuration outwardly from said longitudinal axis for contact with said inner side of the wall of said blood vessel, said blood clot filter with anchor delivery system comprising:

a plurality of elongate, spaced legs each having a distal end and a proximal end, the proximal ends of said elongate legs being secured together adjacent to the longitudinal axis of said blood clot filter, said plurality of elongate spaced legs being formed to extend outwardly away from said longitudinal axis to bring the distal ends thereof into contact with the first inner side of a blood vessel in the expanded configuration of said blood clot filter, one or more of said elongate spaced legs being tubular in configuration with an open distal and an open proximal end,

an elongate anchor shaft mounted for longitudinal movement in each of said tubular elongate legs, each said elongate anchor shaft having first and second opposed ends,

an expandable anchor at the second end of each of said anchor shafts, said expandable anchor having one or more anchor sections with a first collapsed configuration wherein said anchor is substantially coextensive with said anchor shaft and a second expanded configuration wherein said one or more anchor sections extend outwardly from said anchor shaft and loop back to cross and extend beyond said anchor shaft to form one or more closed loops,

said tubular elongate legs each containing said expandable anchor in the first collapsed condition adjacent to the open distal end thereof, and

a shaft support hub connected to the first end of each elongate anchor shaft, said shaft support hub being spaced from the proximal ends of said elongate legs when an expandable anchor in the first collapsed condition is contained in said tubular elongate legs, said shaft support hub being movable toward said proximal ends of said elongate legs to move said anchor shafts longitudinally to propel said expandable anchors out from the open distal ends of said tubular elongate legs and through the wall of a blood vessel.

16. The blood clot filter with anchor delivery system of claim 15 wherein each said expandable anchor includes one or more anchor sections which expand outwardly from said anchor shaft and loop back to cross over said anchor shaft when said expandable anchor is propelled out from the open distal end of a tubular elongate leg and through the wall of a blood vessel, said expandable anchor being oriented such that that the loop formed by each of said one or more anchor sections compresses against said blood vessel wall and changes configuration to form a smaller loop in response to forces which draw said loop against said blood vessel wall.

17. The blood clot filter with anchor delivery system of claim 15 wherein each said expandable anchor includes one or more anchor sections which expand outwardly from said anchor shaft and loop back to cross under said anchor shaft

when said expandable anchor is propelled out from the open distal end of a tubular elongate leg and through the wall of a blood vessel.

18. The blood clot filter with anchor delivery system of claim 15 which includes a drive shaft having a first drive shaft end connected to said shaft support hub to move said shaft support hub relative to the proximal ends of said elongate legs.

19. The blood clot filter with anchor delivery system of claim 18 wherein said drive shaft is mounted for movement within an elongate filter centering shaft having an inner end spaced adjacent to said shaft support hub, said filter centering shaft having a plurality of elongate, spaced, centering arms secured at one end to said centering shaft inner end, said centering arms being adapted to expand outwardly into engagement with said blood vessel wall inner side.

20. The blood clot filter with anchor delivery system of claim 19 wherein said drive shaft includes a second drive shaft end opposite to said first drive shaft end, said second drive shaft end being connected to a propulsion device to cause said drive shaft to propel said shaft support hub toward the proximal ends of said elongate legs.

21. A method for positioning and anchoring a blood clot filter having a plurality of elongate spaced legs adapted to expand outwardly from a filter longitudinal axis to bring a side portion of each of said legs above but adjacent to a free end thereof into contact with the inner surface of a blood vessel wall having an inner and outer surface which includes:

enclosing an expandable anchor in a non expanded state within one or more of said elongate spaced legs,

causing said elongate spaced legs to collapse toward the longitudinal axis of said filter,

transporting said blood clot filter with the legs collapsed through a blood vessel to a desired position,

causing said elongate spaced legs to expand to bring the side portion thereof into contact with the inner surface of said blood vessel wall, and

subsequently propelling said expandable anchor in the non expanded state out of the side portion of one or more of said elongate legs at a position spaced above the free end thereof and through the blood vessel wall for expansion against the outer side of the blood vessel wall.

22. The method of claim 21 which includes propelling said expandable anchor out of the side portion of one or more elongate legs laterally of said elongate legs.

23. A medical device anchor and delivery system for propelling an anchor through a body wall from a first side to a second side where said anchor expands against said second side comprising:

an anchor shaft having a proximal end and a distal end,

an expandable anchor at the distal end of said anchor shaft having one or more anchor sections, said expandable anchor having a first collapsed configuration wherein said anchor is substantially coextensive with said anchor shaft and a second expanded configuration wherein said one or more anchor sections extend outwardly from said anchor shaft,

a shaft support hub connected to the proximal end of said anchor shaft,

an elongate tube having an open entry end and a closed free end opposite to said entry end with a side opening in said tube spaced above said closed free end, said tube containing said anchor shaft and said expandable anchor when said expandable anchor is in said collapsed configuration, and

a drive shaft having a first end for engagement with said shaft support hub, said drive shaft being movable to cause said shaft support hub to move said anchor shaft longitudinally of said elongate tube in the direction of the closed free end thereof to propel said expandable anchor outwardly from the side opening of said tube.

24. The medical device anchor and delivery system of claim 23 wherein said side opening in said tube has a lower edge spaced above the free end of said tube, said tube including an internal curved guidewall extending across said tube from a position opposite to and above said lower edge of said side opening to the lower edge of said side opening, said curved guidewall operating to engage and guide said anchor out through said side opening when said anchor shaft moves longitudinally of said elongate tube in the direction of the free end thereof.

25. A blood clot filter with an anchor delivery system for propelling one or more anchors through the wall of a blood vessel from a first inner side to a second outer side, the blood clot filter having a central longitudinal axis and being collapsible to a collapsed configuration toward said longitudinal axis and expandable to an expanded configuration outwardly from said longitudinal axis for contact with said inner side of the wall of the blood vessel, said blood clot filter with anchor delivery system comprising:

a plurality of elongate spaced legs each having a distal end, a proximal end, and a leg side portion above but adjacent to said distal end, the proximal ends of said elongate legs being secured together adjacent to the longitudinal axis of said blood clot filter, said plurality of elongate spaced legs being formed to extend outwardly away from said longitudinal axis to bring the leg side portions thereof adjacent to the first inner side of a blood vessel in the expanded configuration of the blood clot filter, one or more of said elongate spaced legs having an open proximal end, an internal passage extending from the open proximal end, a closed distal end opposite to said open proximal end. and a side opening to said internal passage formed in said leg side portion above said closed distal end,

an elongate anchor shaft mounted for longitudinal movement in the internal passage of said one or more elongate spaced legs, each said elongate anchor shaft having first and second opposed ends,

an expandable anchor at the second end of each of said anchor shafts having a first collapsed configuration wherein said anchor within said internal passage is substantially coextensive with said anchor shaft and adjacent to said side opening and a second expanded configuration wherein said anchor expands outwardly from said anchor shaft,

and a shaft propulsion unit for engaging the first end of each elongate anchor shaft to move the elongate anchor

shafts longitudinally toward the closed distal ends of said one or more elongate legs to propel said expandable anchors out of the side openings of said one or more elongate legs and through the wall of a blood vessel.

26. The blood clot filter and anchor delivery system of claim 25 wherein said side opening has a lower edge spaced above the distal end of said respective elongate leg, the elongate leg having an internal curved guidewall extending across said internal passage from a position opposite to and above said lower edge of the side opening to the lower edge of the side opening, said curved guidewall operating to engage and guide said anchor out through said side opening when each said anchor shaft moves longitudinally toward the distal end of an elongate leg.

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