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(71)出願人　501481964
アルテリア　メディカル　サイエンス，インコーポレイテッド
アメリカ合衆国　カリフォルニア　９４１２９，　サン　フランシスコ，　ピー．オー．　ボックス　２９４４８，　スイート　１２０，　ビルディング　２２０，　オールド　アーミー　ヘッドクオーターズ，　ザ　プレジディオ
(74)代理人　100078282
弁理士　山本　秀策
(74)代理人　100062409
弁理士　安村　高明
(74)代理人　100113413
弁理士　森下　夏樹

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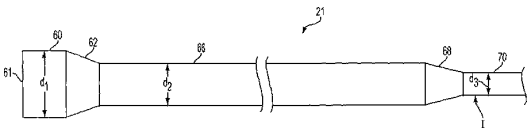
(54)【発明の名称】半径方向に拡張可能な主本体を有するカテーテル

(57)【要約】
本出願において、脈管を閉塞しそしてカテーテル（２１）内の血流を促進するための、装置が提供される。この装置において、カテーテルは、外部シースで覆われた、半径方向に拡張可能な本体を形成する多セクション自己拡張性ワイヤ織物（４６）および閉塞性遠位セクション（６０）を備える。本出願において、塞栓を除去するために本発明の装置を用いる方法もまた、提供される。本出願において、カテーテル内の流れを増大する方法もまた、提供される。



【特許請求の範囲】
【請求項１】
脈管から塞栓を除去するために適切な装置であって、近位セクション、閉塞性遠位セクション、それらの間に延びる主本体、およびそれらを通って延びる管腔を有するカテーテル、および外部シースを備え、該外部シースは、該カテーテルに沿って長手軸方向にスライドするように配置され、改良が、該主本体が、該外部シース内に配置されるときに縮小した送達直径を有し、そして該外部シースから展開されるときに半径方向に拡張された展開直径を有することを包含する、装置。
【請求項２】
前記近位セクションが、固定された直径を備える、請求項１に記載の装置。
【請求項３】
前記閉塞性遠位セクションが、脈管中の流れを閉塞するために適切な、縮小された状態および拡張された状態を備える、請求項１に記載の装置。
【請求項４】
前記閉塞性遠位セクションが、前記拡張された状態で所定の形状を形成するワイヤ織物形態をさらに備える、請求項３に記載の装置。
【請求項５】
前記閉塞性遠位セクションの所定の形状が、展開された場合には、遠位部分では脈管壁と実質的に同一平面上にあり、そして、前記カテーテルの主本体に連結するように近位方向に向かってテーパ状である、請求項４に記載の装置。
【請求項６】
前記閉塞性遠位セクションが、ニチノールを含む、請求項４に記載の装置。
【請求項７】
前記主本体が、複数の個々に圧縮可能なフープを備える、請求項１に記載の装置。
【請求項８】
前記主本体が、ニッケルーチタン合金からなる、請求項７に記載の装置。
【請求項９】
前記個々に圧縮可能なフープが、エラストマーポリマー被覆内に取り囲まれる、請求項７に記載の装置。
【請求項１０】
前記個々の圧縮可能なフープを連結する複数の連結部材をさらに備える、請求項７に記載の装置。
【請求項１１】
前記主本体が、複数の圧縮可能ならせん形状ワイヤを有するらせん形態を備える、請求項１に記載の装置。
【請求項１２】
前記主本体が、ニッケルーチタン合金からなる、請求項１１に記載の装置。
【請求項１３】
前記圧縮可能ならせん形状ワイヤが、エラストマーポリマー被覆内に取り囲まれる、請求項１１に記載の装置。
【請求項１４】
前記圧縮可能ならせん形状ワイヤを連結する複数の連結部材をさらに備える、請求項１１に記載の装置。
【請求項１５】
前記主本体が、前記近位セクションより大きな距離に広がる、請求項１に記載の装置。
【請求項１６】
前記拡張された状態にある主本体の直径が、前記近位セクションの直径より大きい、請求項１に記載の装置。
【請求項１７】
前記外部シースが、最遠位位置で、該外部シース内に前記主本体および前記閉塞性遠位セ

クションを圧縮するように位置決めされる、請求項１に記載の装置。
【請求項１８】
カテーテル内の流れを増大する方法であって、該方法は、
カテーテルを縮小状態に提供する工程であって、ここで、該カテーテルは、近位セクション、閉塞性遠位セクション、これらの間に延びる主本体、およびこれらを通って延びる管腔を備える、工程；
該外部シースを近位方向に引き込んで該閉塞性遠位セクションを展開させる工程；および
外部シースを近位方向にさらに引き込んで、該主本体の半径方向拡張を引き起こす工程、
を包含する、方法。
【請求項１９】
介入手順を実施する工程；および
該介入手順の間に生成された塞栓を、前記カテーテルの管腔中に吸引する工程、
をさらに包含する、請求項１８に記載の方法。
【発明の詳細な説明】
【技術分野】
【０００１】
（関連出願への参照）
本発明は、１９９９年３月１２日に出願された国際出願ＰＣＴ／ＵＳ９９／０５４６９の一部継続出願である、１９９９年６月１４日に出願された米国特許出願第０９／３３３，０７４号の一部継続出願である、１９９９年１０月１５日に出願された米国特許出願第０９／４１８，７２７号の一部継続出願である。
【０００２】
（発明の分野）
本発明は、血管介入の間の塞栓形成に対して保護するため、ならびにカテーテル内の流れ特徴を改善するための、装置および方法に関する。より詳細には、本発明の装置および方法は、半径方向に拡張可能な主本体セクションを有するカテーテルを提供することにより、カテーテル内の血流を促進する。
【背景技術】
【０００３】
（発明の背景）
カテーテルは、断面積が実質的に変化しない材料を用いて一般に製造される。患者の安楽および経管案内の容易さのために、初期のカテーテル断面積は脈管系と比較して比較的に小さいことが、非常に所望される。しかし、介入手順の間には、作動直径が比較的的に小さいままのカテーテルは、いくつかの欠点を有している。
【０００４】
小さいカテーテル断面積の主な欠点は、カテーテル内の流れ抵抗の増加である。比較的小さな管腔を通じて流される高容量の血流は、血球に損傷を生じ得る。塞栓の除去を含む介入手順の間に、血液に加えて大きな塞栓を吸引するとき、その流れはさらに拘束され得る。従って、経管挿入のために小さな送達断面積を有するがより大きな断面積に拡張し得、それ故、カテーテル内の流れ抵抗を低減する、カテーテルを提供することが有益である。
【０００５】
これまで、信頼性のある拡張可能なカテーテルは利用可能ではなかった。Ｌａｍｂｅｒｔらに対する米国特許第５，１０２，４０１号は、少なくとも外側表面が疎水性ポリマーで被覆された熱可塑性エラストマー親水性ポリウレタンを含むカテーテルを記載する。このカテーテルは、水性液体と接触するとき、約３～１５分間でより大きな管腔サイズに拡張する。さらなる刊行物は、体温に付近の温度に上昇される際に軟化する、カテーテルをさらに論議した。
【０００６】
このような先に知られた拡張可能なカテーテルに関連して、いくつかの欠点が存在している。このようなカテーテルは、展開されるとき軟化し得、カテーテルの近位セクションの

ねじれまたは変形を生じ、それによって流れを断つ。さらに、このようなカテーテルは、所望の拡張が生じるために数分間までの待機することを必要とする。従って、構造的に丈夫であり迅速に拡張可能なカテーテルに対する必要性が、残っている。

【０００７】

先に知られた装置および方法は、カテーテルの遠位端に配置された機械的に拡張可能な閉塞性部材を採用することが知られている。同一人に譲渡されたＰａｒｏｄｉに対する米国特許第６，２０６，８６８号は、エラストマーポリマー被覆で覆われた自己拡張性ワイヤメッシュバスケットを備える閉塞性部材を開示する。このカテーテルは、初期には、移動可能なシースで取り囲まれ、そしてシースとともに経管的に最遠位位置に挿入される。このシースは、近位方向に引き込まれてバスケットを展開させ、そしてこのシースをその最遠位位置に移動することにより、バスケットは、シース内に再び折り畳まれる。

【０００８】

Ｐａｒｏｄｉ特許に記載される閉塞性バスケットは、それが、塞栓除去を促進するために脈管壁と実質的に同一平面にある迅速に拡張可能なバスケットを提供するので有利である。しかし、塞栓は、次いで、狭窄の部位から脈管侵入部位まで延びる比較的小さな断面積の管腔中にじょうごのように集中され得る。多くの手順にとって、この距離は、総カテーテル長の大部分を含み得る。従って、血流は、カテーテルの大部分を通じて潜在的に拘束される。

【発明の開示】

【発明が解決しようとする課題】

【０００９】

従前に知られたカテーテルのこれらの欠点を考慮すると、縮小した（ｃｏｎｔｒａｃｔｅｄ）送達直径にて身体内でカテーテルが操縦され得、そして次に血流を促進するためにより大きな直径へとカテーテルが自己拡張し得るように、カテーテルのサイズを半径方向に変化させる装置および方法を提供することが所望され得る。

【００１０】

狭窄の部位から脈管侵入部位まで延びるカテーテルの断面積を拡張することにより、カテーテル内の血液および塞栓の流れを増大する装置および方法を提供することもまた、所望され得る。

【００１１】

化学的変形にも熱的変形にも依存することなく、カテーテルの断面積を迅速に拡張するための装置および方法を提供することが、なおさらに所望され得る。

【００１２】

拡張に際して構造的一体性が弱められない、拡張可能なカテーテルのための装置および方法を提供することがなおさらに所望され得る。

【００１３】

脈管壁と実質的に同一平面にある閉塞性部材により塞栓を効率的に除去するための装置および方法を提供することが、なおさらに所望され得る。

【課題を解決するための手段】

【００１４】

（発明の要旨）

先行する記載を考慮して、縮小送達直径にて身体内でカテーテルが操縦され、そして次に血流を容易にするためにより大きな直径へとインサイチュでカテーテルが自己拡張するように、カテーテルのサイズを半径方向に変えるための装置および方法を提供することが、本発明の目的である。

【００１５】

狭窄の部位から脈管侵入部位まで延びるカテーテルの断面積を拡張することにより、カテーテル内の血液および塞栓の流れを増加するための装置および方法を提供することが、本発明の別の目的である。

【００１６】

化学的変形にも熱的変形にも依存することなく、カテーテルの断面積を迅速に自己拡張するための装置および方法を提供することが、本発明の別の目的である。

【００１７】

拡張に際し構造的一体性が弱められない、拡張可能なカテーテルのための装置および方法を提供することが、本発明のなお別の目的である。

【００１８】

脈管壁と実質的に同一平面上にある閉塞性部材により塞栓を効率的に除去するための装置および方法を提供することが、本発明の別の目的である。

【００１９】

本発明のこれらおよびその他の目的は、塞栓を除去しそしてカテーテル内の血流を促進するために適切な装置および方法を提供することによって、達成される。好ましくは、この装置は、ワイヤ織物（ｗｉｒｅ　ｗｅａｖｅ）形状を備えるカテーテル、血液不透過性膜を提供するためのこの織物（ｗｅａｖｅ）を覆うエラストマーポリマー被覆、および縮小状態にあるカテーテルを覆う外部シースを備える。好ましくは、このカテーテルは、閉塞性遠位セクション、半径方向に拡張する主本体、および脈管侵入部位を通過する固定された直径の近位セクションを備える。

【００２０】

好適な方法では、上記カテーテルは、大腿動脈を通って進められ、そして遠位端が、損傷に対して近位に配置される。このカテーテルを覆う外部シースを近位方向に引き込むとき、閉塞性遠位セクションは、所定の形状に拡張し、脈管壁に対する閉塞性シールを形成する。外部シースをさらに引き込むとき、カテーテルの主本体は、より大きな直径へと迅速に拡張する。外部シースは、脈管侵入部位（例えば、動脈切開部位）に向かって近位方向にさらに引き込まれる。

【００２１】

閉塞性セクションは、前方向勾配流れを閉塞する。そして、狭窄の部位で、後方向勾配流れが、例えば、静脈戻りラインにおける負圧によって誘導され得る。次いで、血管形成術、ステント配置またはアテレクトミーのような介入手順が、、損傷を処置するために実施され得る。この手順の間に生成した塞栓は、その後の除去のためにカテーテルの拡大した管腔中に後方向勾配流れにより向けられる。

【００２２】

本発明のさらなる特徴、その性質および種々の利点は、添付の図面および以下の好適な実施形態の詳細な説明からより明らかである。

【００２３】

（発明の詳細な説明）

図１を参照して、本発明の原理に従って構成された塞栓保護装置２０が記載される。装置２０は、カテーテル２１、外部シース２２、静脈戻りライン３２、管材２９および随意の血液フィルター３０を備える。

【００２４】

カテーテル２１は、止血ポート２３（例えば、Ｔｏｕｈｙ－Ｂｏｒｓｔコネクター）と連通する管腔４０、および血液出口ポート２８を備える。管材２９は、血液出口ポート２８を、フィルター３０および静脈戻りライン３２の血液入口ポート３１と接続する。

【００２５】

好ましくは、外部シース２２は、クリップ２５、長手軸方向スリット２７、および中実遠位セクション３５を備える。クリップ２５は、外部シース２２の近位端に固定され、そして図１に示されるように、ロック状態にあるカテーテル２１に係合し得るか、または力が付与されたときに、カテーテル２１から脱係合し得る。以下に本明細書で記載されるように、長手軸方向スリット２７は、外部シース２２がカテーテル２１から脱係合することを可能にし、血液出口ポート２８をも止血ポート２３をも妨害することなく外部シース２２の近位方向引き込みを可能にする。

【００２６】

止血ポート２３および管腔４０は、バルーン血管形成術カテーテル、アテレクトミーデバイスおよびステント送達システムのような介入デバイスが、管腔４０を通過して閉塞の部位まで進められることを可能にするサイズである。

【００２７】

静脈戻りライン３２は、止血ポート３３、血液入口ポート３１およびポート３３と３１と連通する管腔、および先端３４を備える。静脈戻りライン３２は、静脈導入器カテーテルについてそれ自体公知である様式で構築され得る。管材２９は、適切な長さのシリコーンのような生体適合性材料を含み得る。あるいは、管材２９は省略され得、そしてカテーテル２１の血液出口ポート２８および静脈戻りライン３２の血液入口ポート３１は、フィルター３０の端部に係合するかまたは互いに係合するかのいずれかである長さであり得る。

【００２８】

図２を参照して、カテーテル２１の拡張可能な特徴が、より詳細に記載される。図２のＡは、外部シース２２内で縮小された状態にある、管腔４０を有するカテーテル２１を示す。このデバイスは、経管的に挿入され得、そして縮小された状態で脈管Ｖ内に位置決めされ得る。カテーテル２１の遠位セクションは、拡張可能なワイヤ織物（ｗｉｒｅ　ｗｅａｖｅ）形状で構築され得る。好適な実施形態では、このワイヤ織物（ｗｉｒｅ　ｗｅａｖｅ）は、形状記憶保持材料（例えば、ニッケルチタン合金（当該分野でニチノール（Ｎｉｔｉｎｏｌ）として一般に知られる））を含む。

【００２９】

一般に、ニチノール（Ｎｉｔｉｎｏｌ）の使用は、（例えば、マンドレル上でニチノール（Ｎｉｔｉｎｏｌ）部材を圧迫することによるか、または所望の形状に固定すること、そして次に、それ自体が公知である適切な熱処理を施すことによる）一片のニチノール（Ｎｉｔｉｎｏｌ）における注文形状のセッティングを必要とする。

【００３０】

好ましくは、カテーテル２１は、ラテックス、ポリウレタンまたはポリイソプレンのような、エラストマーポリマー４５で取り囲まれる。カテーテル２１の形状は、初期には外部シース２２により拘束されている。外部シース２２を近位方向に引き込むとき、図２Ｂに示されるように、ワイヤ４３および管腔４０が半径方向に拡張し、そして線状に拡張し得、口５２を有する閉塞性遠位セクション４２を形成する。エラストマーポリマー４５は伸張して、拡張された形状に合致する。好ましくは、所定の形状は、角度をもつテーパ４４およびフープ４７を含む。

【００３１】

閉塞性遠位セクション４２の半径方向拡張は、その外直径が、前方向勾配（ａｎｔｅｇｒａｄｅ）流れを閉塞するように脈管Ｖの内膜と実質的に同一平面上にあるようである。さらに、閉塞性遠位セクション４２と脈管Ｖとの間の表面接触は、このデバイスを有効に係留し得る。

【００３２】

角度をもつテーパ４４は、カテーテル２１の口５２から主本体４６中へと血液および塞栓の指向させることを容易にする。さらに、角度をもつテーパ４４は、外部シース２２が、閉塞性遠位セクション４２の上を遠位方向にスライドし、このシース内でそのセクションを有効に折り畳む（縮小させる）ことを可能にする。

【００３３】

フープ４７は、主本体４６から閉塞性遠位セクション４２を分離するために用いられ得る。なぜなら、この２つのセクションは、好ましくは、別個の拡張された直径を有するからである。主本体４６は、初期には、外部シース２２内で周辺が圧縮されているワイヤ形態を含む。図２Ｃに示されるように、外部シース２２がさらに近位方向に引き込まれるとき、主本体４６は、脈管Ｖ内で半径方向に拡張する。ワイヤ４８は、例えば、本明細書で上記に記載したように、形状記憶合金を熱処理することにより確立され得る所定の形状に、半径方向に拡張する。主本体４６の例示のワイヤ形態は、本明細書で以下の図５に記載されている。

【００３４】
図３を参照して、カテーテル２１の略側面図が、完全に展開された状態で描かれる。カテーテル２１は、閉塞性遠位セクション６０、主本体６６、近位セクション７０、および角度をもつテーパ６２および角度をもつテーパ６８を備える。閉塞性遠位セクション６０および主本体６６は、拡張された直系d_1およびd_2をそれぞれ備え、その一方、近位セクション７０は、経管挿入直径d_3を備える。
【００３５】
閉塞性遠位セクション６０および主本体６６は、初期には、外部シース２２内で、それらの収縮直径が近位セクション７０の経管挿入直径d_3に実質的に等しいように折り畳まれている。次いで、カテーテル２１は、身体中に皮下的および経管的に挿入され得、そして図２に示されるように、展開されるまで、直径d_3で脈管系内で操縦され得る。
【００３６】
展開された状態では、d_1は（口６１を通る以外の）標的脈管中の血流を閉塞するサイズである。直径d_1は、脈管の範囲にある流れを閉塞するために拡張し得る。閉塞性遠位セクション６０は、口６１を経由しての大きな塞栓の除去を容易にする。角度をもつテーパ６２は、閉塞性遠位セクション６０から主本体６６中へと血液および塞栓を指向することを支援する。次いで、血液および塞栓は、輸送直径d_3にて近位方向に指向される。
【００３７】
有利には、主本体６６により提供される拡大された管腔は、損傷近傍の位置から脈管侵入部位Ｉに対してわずかに遠位方向にある位置に、好ましくはカテーテル２１の全体長さの大部分に広がる距離、血液を輸送する。従って、流れ抵抗は、このカテーテルの大部分を通じて低減され得る。
【００３８】
角度をもつテーパ６８は、血液を、主本体６６から近位セクション７０中へとじょうごのように集中させる。好ましくは、近位セクション７０は、経管挿入直径d_3で固定されたままであり、そして、血液出口ポート２８から脈管侵入部位Ｉに対してわずかに遠位方向にある位置まで延びる。
【００３９】
図４のＡからＤを参照して、本発明に従う装置の使用が記載されている。図４において、損傷Ｓが、身体の脈管Ｖ内に位置している。第１の工程では、初期には外部シース８６内で圧縮されているカテーテル８８は、図４のＡに示されるように、皮下的かつ経管的にか、または外科的切断を介してかのいずれかで、損傷Ｓに対して近位方向の位置まで挿入される。本明細書で上記のように、外部シース８６は、次いで、図４Ｂに示されるように、近位方向に引き込まれ、閉塞性遠位セクション９２を展開させ、そしてさらに近位方向に引き込まれ、主本体９８を半径方向に拡張する。
【００４０】
次いで、静脈戻りライン３２が、皮下的にかまたは外科的切断を介してかのいずれかで、患者の大腿静脈中に導入され得る。次いでフィルター３０が、管材２９を用いてカテーテル２１の血液出口ポート２８と静脈戻りライン３２の血液入口ポート３１との間に接続され、そしてすべての空気がこのラインから取り除かれる。一旦この回路が閉鎖されると、拡張期の間の静脈戻りライン３２中の負圧力が、カテーテル２１の管腔９０を通る血液の低速度連続流れを確立する。図４のＢに示されるように、閉塞性遠位セクション９２の展開は、脈管Ｖ中で流れる前方向勾配を閉塞し、その一方、管腔９０を通る、例えば、静脈戻りライン３２からの負圧力は、損傷の部位における後方向勾配流れを誘導する。
【００４１】
静脈圧力と動脈圧力との間の差異に起因するこの低速度連続流れは、介入手順の間中、継続する。詳細には、血液は、カテーテル２１の管腔９０および血液出口ポート２８を通り、生体適合性管材２９を通ってフィルター３０へと通り、そして静脈戻りライン３２の血液入口ポート３１中へと通り、そこで、血液は、遠隔静脈中に再灌流される。本発明による（任意の拡大器具の膨張の間を除く）再灌流をともなう連続血流は、血液損失が有意に

減少した効率的な塞栓除去を提供する。

【００４２】

図４のＣを参照すると、閉塞性遠位セクション９２が展開され、そして脈管Ｖ中に後方向勾配流れが確立されており、損傷Ｓを処置する介入手順が実施され得る。この手順は、当該技術分野で一般に知られた任意のものであり得る。例えば、バルーン血管形成が適用され得、それによって、バルーン１０２を有する従来の血管形成術バルーンカテーテル１０１が、止血ポート２３および管腔９０を通して装填され得、次いで、損傷Ｓ内に位置決めされ得る。次いで、止血ポート２３が閉鎖され、そしてバルーン１０２が膨張されて損傷Ｓを処置する。次いで、バルーン１０２は、損傷Ｓの十分な除去または破壊に際して収縮（ｄｅｆｌａｔｅ）される。

【００４３】

図４のＤを参照して、上記手順の間に生成された塞栓Ｅは、上記の確立された後方向勾配流れを介して管腔９０中に向けられる。角度をもつ管腔９６は、血液および塞栓Ｅを主本体９８中にじょうごのように集める。血液および塞栓Ｅは、カテーテル２１内を近位方向に移動し、その後、塞栓Ｅは、次いでフィルター３０を経由して除去され得る。

【００４４】

終了に際し、外部シース８６は、カテーテル２１の長さに沿って遠位方向に進行されて、主本体９８および遠位セクション９２がこのシース内に折り畳まれ得、この後、脈管Ｖ内で前方向勾配流れが再確立されるようにされる。次いで、カテーテル２１は、経管的に引き込まれ得、そしてこの器具は、患者の脈管から除去され得る。

【００４５】

図５を参照して、本発明による半径方向に拡張する主本体の代替形状が、記載される。図５のＡにおいて、フープ形状が示され、このフープ形状において、カテーテル２１の主本体１１０は、いくつかの個々のフープ１１６を備える。個々のフープ１１６は、それらのフープ１１６が、領域１１２で示されるように、圧縮力Ｆ（例えば、外部シース２２により提供される力）によって、周辺が圧縮され得るように設計されている。圧縮力Ｆが取り除かれたとき、フープ１１６は、より大きな所定の直径に拡張する。好適な実施形態では、フープ１１６は、本明細書で上記に記載したような方法に従って、形状記憶材料（例えば、ニチノール（Ｎｉｔｉｎｏｌ））から製造される。

【００４６】

好ましくは、個々のフープ１１６は、エラストマーポリマー被覆１１３内に取り囲まれ、拡張可能な血液不透過性膜を形成する。個々のフープ１１６は、さらなる構造的安定性のために連結部材１１８を介して隣接するフープに連結され得る。

【００４７】

あるいは、主本体１１０は、複数の圧縮可能ならせん形状ワイヤを備え得る。図５のＢに示されるように、ワイヤ１２６および１２８は、それらのワイヤが主本体１１０の長さに沿って長い連続らせんを形成するような角度をもっている。好ましくは、この圧縮可能ならせん形状のワイヤは、形状記憶材料を含み、そしてエラストマーポリマー１１３で被覆され得る。連結部材１２２は、隣接するらせん間のさらなる支持を提供するために用いられ得る。

【００４８】

ここで、図６を参照すると、外部シース１４０の近位方向引き込みを可能にする機構が、記載される。図６のＡに示されるように、外部シース１４０は、クリップ１４２、長手軸方向スリット１４４、および中実遠位セクション１４６を備える。

【００４９】

図６のＢに示されるように、クリップ１４２は、ロック状態にてカテーテル１４１を係合するようなサイズである。好ましくは、クリップ１４２は、力Ｆ（すなわち、医師により付与される手動力）が、示された方向に付与されるときに変形し得る、従順なゴム様材料を含む。クリップ１４２の壁１４８は、クリップ１４２がカテーテル１４１から脱係合することを可能にするように離れ得る。

【００５０】
好ましくは、外部シース１４０の長手軸方向スリット１４４は、フラップ１５２およびフラップ１５４を備える。縮小状態では、フラップ１５２およびフラップ１５４は、図６のＡの断面線Ａ－Ａを通る断面図からの図６のＣに示されるように、重複してカテーテル１４１を取り囲む。力Ｆが付与されたとき、フラップ１５２およびフラップ１５４は、断面線Ａ－Ａを通る断面図からの図６のＤに示されるように、カテーテル１４１から脱係合する。
【００５１】
中実遠位セクション１４６は、外部シース１４０が近位方向にさらに引き込まれたときに、外部シース１４０を案内する。この手順が終了するとき、外部シース１４０は、フラップ１５２およびフラップ１５４がもう一度重複するように遠位方向に進行する。この重複状態では、外部シース１４０は、外部シースが遠位方向に進行するにつれてその外部シース内にカテーテル１４１を引き込む。次いで、クリップ１４２は、カテーテル１４１を再係合し得る。
【００５２】
本発明の好適な例示の実施形態を上記に記載したが、本発明から逸脱することなく、種々の変更および改変がその中でなされ得ることは当業者に明らかである。添付の特許請求の範囲は、本発明の真の思想および範囲内に入るそのような変更および改変のすべてを網羅することが、意図される。
【図面の簡単な説明】
【００５３】
【図１】図１は、折り畳まれた（ｃｏｌｌａｐｓｅｄ）送達状態にある、本発明に従って構成された装置の側面図である。
【図２】図２Ａ～Ｃは、カテーテルの拡張可能な特徴の概略図である。
【図３】図３は、完全に展開された状態にある、本発明に従って構成されたカテーテルの側面図である。
【図４】図４Ａ～４Ｄは、本発明のカテーテルを用いる方法の工程を示す。
【図５】図５Ａ～５Ｂは、カテーテルの拡張可能な本体の代替形状を示す。
【図６】図６Ａ～６Ｄは、本発明の外部シースの近位方向引き込みを可能にする機構を示す。

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(71) Applicant: ARTERIA MEDICAL SCIENCE, INC. [US/US]; The Presidio, Old Army Headquarters, Building 220, Suite 120, P.O. Box 29450, San Francisco, CA 94129 (US).

(72) Inventor: HOGENDIJK, Michael; 501 Forest Avenue #904, Palo Alto, CA 94301 (US).

(74) Agents: PISANO, Nicola, A. et al.; c/o Fish & Neave, 1251 Avenue of the Americas, New York, NY 10020 (US).

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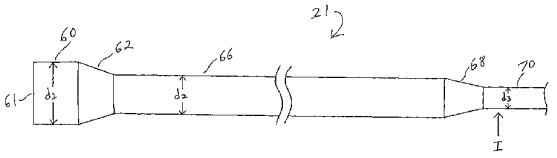
(54) Title: CATHETER HAVING RADIALLY EXPANDABLE MAIN BODY



(57) Abstract: Apparatus for occluding a vessel and enhancing blood flow within a catheter are provided, wherein a catheter comprises a multi-section self-expanding wire weave forming a radially expandable body and an occlusive distal section, covered with an elastomeric polymeric coating, and disposed within an outer sheath. Methods of using the apparatus of the present invention to remove emboli also are provided.

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CATHETER HAVING RADIALLY EXPANDABLE MAIN BODY

Reference to Related Applications

The present application is a continuation-in-part of U.S. patent application Serial No. 09/418,727, filed October 15, 1999, which is a continuation-in-part of U.S. patent application Serial No. 09/333,074, filed June 14, 1999, which is a continuation-in-part of International Application PCT/US99/05469, filed March 12, 1999.

Field Of The Invention

The present invention relates to apparatus and methods for protecting against embolization during vascular interventions and improving flow characteristics within a catheter. More particularly, the apparatus and methods of the present invention facilitate blood flow within a catheter by providing a catheter having a radially expandable main body section.

Background Of The Invention

Catheters are commonly manufactured using materials that do not substantially change in cross-sectional area. It is highly desirable that the initial cross-sectional catheter area be relatively small compared to the vasculature for patient comfort and ease of transluminal guidance. However, catheters in which the working diameters remain relatively small have several disadvantages during interventional procedures.

A primary disadvantage of a small cross-sectional catheter area is increased flow resistance within the catheter. A high volume of blood flow being forced through a relatively small lumen may cause damage to blood cells. During interventional procedures involving the removal of emboli, the flow may be further constrained when aspirating large emboli in addition to blood. It therefore would be advantageous to provide a catheter having a small delivery cross-sectional area for transluminal insertion, but which is capable of expanding to a larger cross-sectional area, thus reducing flow resistance within the catheter.

Heretofore, no reliable expandable catheters have been available. U.S. Patent No. 5,102,401 to Lambert et al. describes a catheter comprising a thermoplastic elastomeric hydrophilic polyurethane coated on at least the outside surface with a hydrophobic polymer. The catheter expands to a larger lumen size in about 3 to 15 minutes when contacted with an aqueous liquid. Additional publications have further discussed catheters which soften upon being raised to a temperature approaching body temperature.

There are several drawbacks associated with

such previously known expandable catheters. Such catheters can soften when deployed, resulting in kinking or deformation of the proximal section of the catheter, thereby cutting off flow. Additionally, such catheters require a wait of up to several minutes for the desired expansion to occur. Accordingly, there remains a need for a structurally durable, rapidly expandable catheter.

Previously-known apparatus and methods are known that employ a mechanically expandable occlusive element disposed at the distal end of a catheter. Commonly assigned U.S. Patent No. 6,206,868 to Parodi discloses an occlusive element comprising a self-expanding wire mesh basket covered with an elastomeric polymer coating. The catheter is initially surrounded by a movable sheath, and is inserted transluminally with the sheath at a distalmost position. The sheath is retracted proximally to cause the basket to deploy, and the basket is again collapsed within the sheath by moving the sheath to its distalmost position.

The occlusive basket described in the Parodi patent is advantageous because it provides a rapidly expandable basket that is substantially flush with the vessel wall to enhance emboli removal. However, emboli then may be funneled into a relatively small cross-sectional area lumen that extends from the site of the stenosis to the vascular entry site. For many procedures, this distance may comprise the vast majority of the overall catheter length. Accordingly, blood flow is potentially constrained throughout the majority of the catheter.

In view of these drawbacks of previously known catheters, it would be desirable to provide apparatus and methods for radially varying the size of

a catheter so that the catheter can be maneuvered within the body at a contracted delivery diameter and then self-expands to a larger diameter to facilitate blood flow.

It also would be desirable to provide apparatus and methods for enhancing the flow of blood and emboli within a catheter by expanding the cross-sectional area of the catheter that extends from the site of the stenosis to the vascular entry site.

It still further would be desirable to provide apparatus and methods for rapidly expanding the cross-sectional area of a catheter without relying on chemical or thermal transformations.

It still further would be desirable to provide apparatus and methods for an expandable catheter whereby the structural integrity is not compromised upon expansion.

It still further would be desirable to provide apparatus and methods for efficiently removing emboli by means of an occlusive member that is substantially flush with the vessel wall.

Summary Of The Invention

In view of the foregoing, it is an object of the present invention to provide apparatus and methods for radially varying the size of a catheter so that the catheter can be maneuvered within the body at a contracted delivery diameter and then self-expands to a larger diameter in situ to facilitate blood flow.

It is another object of the present invention to provide apparatus and methods for enhancing the flow of blood and emboli within a catheter by expanding the cross-sectional area of the catheter that extends from the site of the stenosis to the vascular entry site.

It is another object of the present invention to provide apparatus and methods for rapidly self-expanding the cross-sectional area of a catheter without relying on chemical or thermal transformations.

It is yet another object of the present invention to provide apparatus and methods for an expandable catheter whereby the structural integrity is not compromised upon expansion.

It is another object of the present invention to provide apparatus and methods for efficiently removing emboli by means of an occlusive member that is substantially flush with the vessel wall.

These and other objects of the present invention are accomplished by providing apparatus and methods suitable for removing emboli and facilitating blood flow within a catheter. The apparatus preferably comprises a catheter having a wire weave configuration, an elastomeric polymer coating covering the weave to provide a blood impermeable membrane, and an outer sheath covering the catheter in a contracted state. The catheter preferably comprises an occlusive distal section, a radially expanding main body, and a fixed diameter proximal section that passes through the vascular entry site.

In a preferred method, the catheter is advanced through the femoral artery and the distal end is positioned proximal to a lesion. As the outer sheath covering the catheter is retracted proximally, the occlusive distal section expands to a predetermined shape to form an occlusive seal against the vessel wall. As the outer sheath is further retracted, the main body of the catheter expands radially to a larger diameter. The outer sheath is further retracted proximally toward the vascular entry site, e.g., the

arteriotomy.

The occlusive distal section occludes antegrade flow, and retrograde flow may be induced at the site of the stenosis, e.g., via negative pressure in a venous return line. An interventional procedure, such as angioplasty, stenting or atherectomy, then may be performed to treat the lesion. Emboli generated during the procedure are directed via the retrograde flow into the enlarged lumen of the catheter for subsequent removal.

Brief Description Of The Drawings

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments, in which:

FIG. 1 is a side view of apparatus constructed in accordance with the present invention in a collapsed delivery state;

FIGS. 2A-2C are schematic illustrations of the expandable features of the catheter;

FIG. 3 is a side view of a catheter constructed in accordance with the present invention in a fully deployed state;

FIGS. 4A-4D depict method steps of using the catheter of the present invention;

FIGS. 5A-5B illustrate alternative configurations of the expandable body of the catheter; and

FIGS. 6A-6D describe a mechanism for enabling proximal retraction of the outer sheath of the present invention.

Detailed Description Of The Invention

Referring to FIG. 1, embolic protection apparatus 20 constructed in accordance with principles of the present invention is described. Apparatus 20 comprises catheter 21, outer sheath 22, venous return line 32, tubing 29 and optional blood filter 30.

Catheter 21 comprises lumen 40 that communicates with hemostatic port 23, e.g., a Touhy-Borst connector and blood outlet port 28. Tubing 29 couples blood outlet port 28 to filter 30 and blood inlet port 31 of venous return line 32.

Outer sheath 22 preferably comprises clip 25, longitudinal slit 27 and solid distal section 35. Clip 25 is affixed to the proximal end of outer sheath 22 and may engage catheter 21 in a locked state, as shown in FIG. 1, or may disengage from catheter 21 when a force is applied. As described hereinbelow, longitudinal slit 27 permits outer sheath 22 to disengage from catheter 21, to allow proximal retraction of outer sheath 22 without interfering with blood outlet port 28 or hemostatic port 23.

Hemostatic port 23 and lumen 40 are sized to permit interventional devices, such as balloon angioplasty catheters, atherectomy devices and stent delivery systems, to be advanced through lumen 40 to the site of the occlusion.

Venous return line 32 includes hemostatic port 33, blood inlet port 31 and a lumen that communicates with ports 33 and 31 and tip 34. Venous return line 32 may be constructed in a manner per se known for venous introducer catheters. Tubing 29 may comprise a suitable length of a biocompatible material, such as silicone. Alternatively, tubing 29 may be omitted and blood outlet port 28 of catheter 21 and

blood inlet port 31 of venous return line 32 may be lengthened to engage either end of filter 30 or each other.

Referring to FIGS. 2, the expandable features of catheter 21 are described in greater detail. FIG. 2A depicts catheter 21 having lumen 40 in a contracted state within outer sheath 22. The device may be transluminally inserted and positioned within a vessel V in the contracted state. The distal section of catheter 21 may be constructed in an expandable wire weave configuration. In a preferred embodiment, the wire weave comprises a shape-memory retaining material, for example, a Nickel Titanium alloy (commonly known in the art as Nitinol).

The use of Nitinol generally requires the setting of a custom shape in a piece of Nitinol, e.g., by constraining the Nitinol element on a mandrel or fixture in the desired shape, and then applying an appropriate heat treatments, which are per se known.

Catheter 21 preferably is enclosed by elastomeric polymer 45, such as latex, polyurethane or polyisoprene. The shape of catheter 21 is initially constrained by outer sheath 22. As outer sheath 22 is retracted proximally, wires 43 and lumen 40 expand radially and may expand linearly to form occlusive distal section 42 having mouth 52, as shown in FIG. 2B. Elastomeric polymer 45 stretches to conform to the expanded shape. The predetermined configuration preferably comprises angled taper 44 and hoop 47.

The radial expansion of occlusive distal section 42 is such that its outer diameter is substantially flush with the intima of vessel V to occlude antegrade flow. Additionally, the surface contact between occlusive distal section 42 and vessel

V may effectively anchor the device.

Angled taper 44 facilitates direction of blood and emboli from mouth 52 into main body 46 of catheter 21. Additionally, angled taper 44 permits outer sheath 22 to slide distally over occlusive distal section 42 to effectively collapse that section within the sheath.

Hoop 47 may be used to separate occlusive distal section 42 from main body 46, as the two sections preferably have distinct expanded diameters. Main body 46 comprises a wire configuration that is initially compressed circumferentially within outer sheath 22. As outer sheath 22 is further retracted proximally, main body 46 expands radially within vessel V, as shown in FIG. 2C. Wires 48 expand radially to a predetermined shape that may be established, for example, by heat treating a shape-memory alloy as described hereinabove. Exemplary wire configurations for main body 46 are described in FIGS. 5 hereinbelow.

Referring now to FIG. 3, a schematic side view of catheter 21 is depicted in a fully deployed state. Catheter 21 comprises occlusive distal section 60, main body 66, proximal section 70, and angled tapers 62 and 68. Occlusive distal section 60 and main body 66 comprise expanded diameters d_1 and d_2, respectively, while proximal section 70 comprises transluminal insertion diameter d_3.

Occlusive distal section 60 and main body 66 are initially collapsed within outer sheath 22 such that their contracted diameters are substantially equal to the transluminal insertion diameter d_3 of proximal section 70. Catheter 21 then may be percutaneously and transluminally inserted into the body and maneuvered

within the vasculature at diameter d_3 until deployed, as depicted in FIGS. 2.

In the deployed state, d_1 is sized to occlude blood flow in the targeted vessel (other than through mouth 61). Diameter d_1 may expand to occlude flow in a range of vessels. Occlusive distal section 60 facilitates removal of large emboli via mouth 61. Angled taper 62 assists in directing blood and emboli from occlusive distal section 60 into main body 66. Blood and emboli then are directed proximally at transport diameter d_3.

Advantageously, the enlarged lumen provided by main body 66 transports blood from a location near the lesion to a location slightly distal to vascular entry site I, a distance that preferably spans the majority of the overall length of catheter 21. Accordingly, flow resistance may be reduced throughout the majority of the catheter.

Angled taper 68 funnels blood from main body 66 into proximal section 70. Proximal section 70 preferably remains fixed at transluminal insertion diameter d_3 and extends from blood outlet port 28 to a location slightly distal to vascular entry site I.

Referring to FIGS. 4A-4D, use of apparatus in accordance with the present invention is described. In FIGS. 4, lesion S is located within a vessel V of the body. In a first step, catheter 88, initially compressed within outer sheath 86, is inserted either percutaneously and transluminally or via a surgical cut-down, to a position proximal to lesion S, as shown in FIG. 4A. As described hereinabove, outer sheath 86 then is retracted proximally to cause occlusive distal section 92 to deploy, as shown in FIG. 4B, and further

retracted proximally to radially expand main body 98.

Venous return line 32 then may be introduced into the patient's femoral vein, either percutaneously or via a surgical cut-down. Filter 30 then is coupled between blood outlet port 28 of catheter 21 and blood inlet port 31 of venous return line 32 using tubing 29, and any air is removed from the line. Once this circuit is closed, negative pressure in venous return line 32 during diastole will establish a low rate continuous flow of blood through lumen 90 of catheter 21. As shown in FIG. 4B, the deployment of occlusive distal section 92 occludes antegrade flown in vessel **V**, while the negative pressure through lumen 90, e.g., from venous return line 32, induces retrograde flow at the site of the lesion.

This low rate continuous flow due to the difference between venous pressure and arterial pressure will continue throughout the interventional procedure. Specifically, blood passes through lumen 90 and blood outlet port 28 of catheter 21, through biocompatible tubing 29 to filter 30, and into blood inlet port 31 of venous return line 32, where it is reperfused into the remote vein. Continuous blood flow (except during inflation of any dilatation instruments) with reperfusion in accordance with the present invention provides efficient embolic removal with significantly reduced blood loss.

Referring to FIG. 4C, with occlusive distal section 92 deployed and retrograde flow established in vessel **V**, an interventional procedure to treat lesion **S** may be performed. The procedure may be any commonly known in the art. For example, balloon angioplasty may be applied whereby conventional angioplasty balloon catheter 101 having balloon 102 may be loaded through

hemostatic port 23 and lumen 90, then positioned within lesion **S**. Hemostatic port 23 then is closed, and balloon 102 is inflated to treat lesion **S**. Balloon 102 then is deflated upon satisfactory removal or disruption of lesion **S**.

Referring to FIG. 4D, emboli **E** generated during the procedure are directed into lumen 90 via the established retrograde flow. Angled taper 96 funnels blood and emboli **E** into main body 98. Blood and emboli **E** travel proximally within catheter 21, and emboli **E** may be subsequently removed via filter 30.

Upon completion, outer sheath 86 may be advanced distally along the length of catheter 21 to collapse main body 98 and occlusive distal section 92 within the sheath, which in turn causes antegrade flow to become re-established in vessel **V**. Catheter 21 then may be retracted transluminally and the apparatus may be removed from the patient's vessel.

Referring to FIGS. 5, alternative configurations of the radially expanding main body in accordance with the present invention are described. In FIG. 5A, a hoop configuration is shown wherein main body 110 of catheter 21 comprises several individual hoops 116. Individual hoops 116 are designed such that they may be compressed circumferentially by a compressive force **F**, e.g., the force provided by outer sheath 22, as depicted in region 112. When compressive force **F** is removed, hoops 116 expand to a larger, predetermined diameter. In a preferred embodiment, hoops 116 are manufactured from a shape-memory material, e.g, Nitinol, according to methods described hereinabove.

Individual hoops 116 preferably are enclosed within elastomeric polymer coating 113 to form an expandable, blood impermeable membrane. Individual hoops 116 may be connected to adjacent hoops via linkages 118 for additional structural stability.

Alternatively, main body 110 may comprise a plurality of compressible, spiral-shaped wires. As shown in FIG. 5B, wires 126 and 128 are angled such that they form long, continuous spirals along the length of main body 110. The compressible, spiral-shaped wires preferably comprise a shape memory material and may be coated with elastomeric polymer 113. Linkages 122 may be used to provide additional support between adjacent spirals.

Referring now to FIGS. 6, a mechanism for allowing proximal retraction of outer sheath 140 is described. Outer sheath 140 comprises clip 142, longitudinal slit 144 and solid distal section 146, as shown in FIG. 6A.

Clip 142 is sized to engage catheter 141 in a locked state, as shown in FIG. 6B. Clip 142 preferably comprises a compliant rubber-like material that may deform when a force **F** is applied in the direction indicated, i.e., a manual force applied by the physician. Walls 148 of clip 142 may part to allow clip 142 to disengage from catheter 141.

Longitudinal slit 144 of outer sheath 140 preferably comprises flaps 152 and 154. In a contracted state, flaps 152 and 154 overlap to enclose catheter 141, as shown in FIG. 6C from a sectional view through section line A--A of FIG. 6A. As a force **F** is applied, flaps 152 and 154 disengage from catheter 141, as shown in FIG. 6D from a sectional view through section line A--A.

Solid distal section 146 guides outer sheath 140 as it is further retracted proximally. When the procedure is completed, outer sheath 140 is advanced distally such that flaps 152 and 154 once again overlap. In this overlapping state, outer sheath 140 retracts catheter 141 within the sheath as the sheath is advanced distally. Clip 142 then may re-engage catheter 141.

While preferred illustrative embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made therein without departing from the invention. The appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

What Is Claimed Is:

1. Apparatus suitable for removing emboli from a vessel, the apparatus comprising a catheter having a proximal section, an occlusive distal section, a main body extending therebetween, and a lumen extending therethrough, and an outer sheath, the outer sheath disposed to slide longitudinally along the catheter, the improvement comprising that the main body has a contracted delivery diameter when disposed within the outer sheath and a radially expanded deployed diameter when deployed from the outer sheath.

2. The apparatus of claim 1 wherein the proximal section comprises a fixed diameter.

3. The apparatus of claim 1 wherein the occlusive distal section comprises a contracted state and an expanded state suitable for occluding flow in a vessel.

4. The apparatus of claim 3 wherein the occlusive distal section further comprises a wire weave configuration that forms a predetermined shape in the expanded state.

5. The apparatus of claim 4 wherein the predetermined shape of the occlusive distal section, when deployed, is substantially flush with the vessel wall at a distal portion and tapers in proximally to connect to the main body of the catheter.

6. The apparatus of claim 4 wherein the occlusive distal section comprises Nitinol.

7. The apparatus of claim 1 wherein the main body comprises a plurality of individually compressible hoops.

8. The apparatus of claim 7 wherein the main body consists of a nickel-titanium alloy.

9. The apparatus of claim 7 wherein the individually compressible hoops are enclosed within an elastomeric polymer coating.

10. The apparatus of claim 7 further comprising a plurality of linkages connecting the individually compressible hoops.

11. The apparatus of claim 1 wherein the main body comprises a spiral configuration having a plurality of compressible spiral-shaped wires.

12. The apparatus of claim 11 wherein the main body consists of a nickel-titanium alloy.

13. The apparatus of claim 11 wherein the compressible spiral-shaped wires are enclosed within an elastomeric polymer coating.

14. The apparatus of claim 11 further comprising a plurality of linkages connecting the compressible spiral-shaped wires.

15. The apparatus of claim 1 wherein the main body spans a greater distance than the proximal section.

16. The apparatus of claim 1 wherein the diameter of the main body in an expanded state is larger than the diameter of the proximal section.

17. The apparatus of claim 1 wherein the outer sheath is positioned in a distalmost position to compress the main body and occlusive distal section within the outer sheath.

18. A method for enhancing flow within a catheter, the method comprising:

providing a catheter in a contracted state, wherein the catheter comprises a proximal section, an occlusive distal section, a main body extending therebetween, and a lumen extending therethrough;

retracting an outer sheath proximally to deploy the occlusive distal section; and

further retracting the outer sheath proximally to cause radial expansion of the main body.

19. The method of claim 18 further comprising:

performing an interventional procedure; and

aspirating emboli generated during the interventional procedure into the lumen of the catheter.

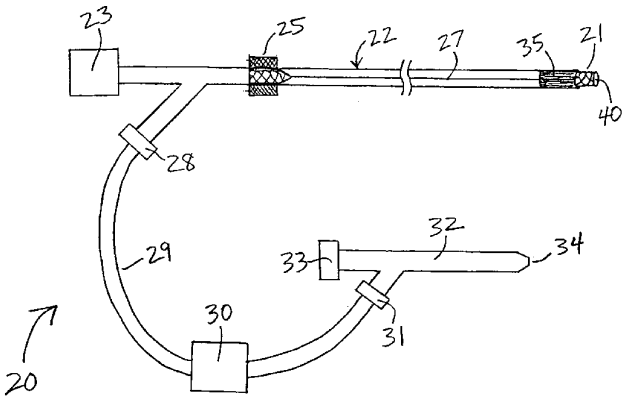

FIG. 1

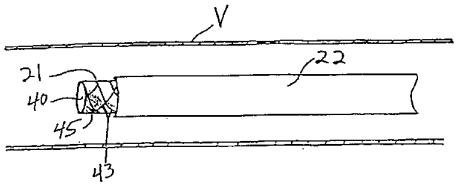

FIG. 2A

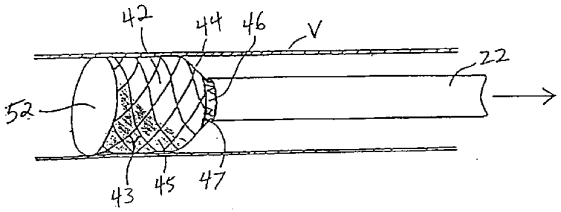

FIG. 2B

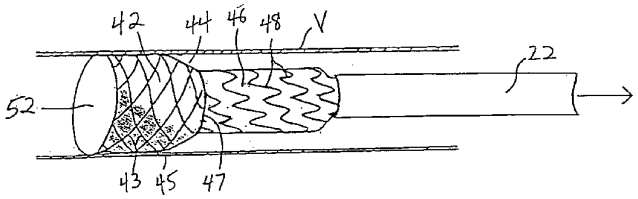

FIG. 2C

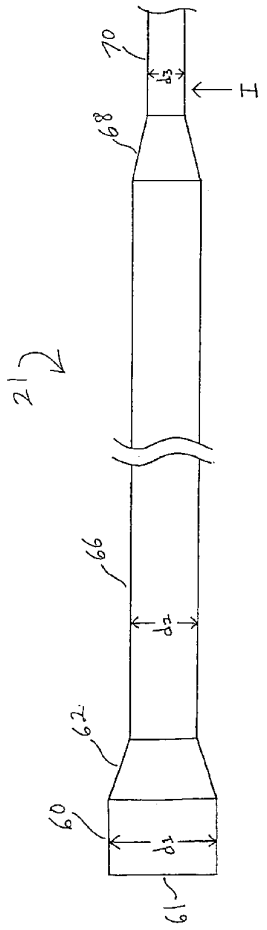

FIG. 3

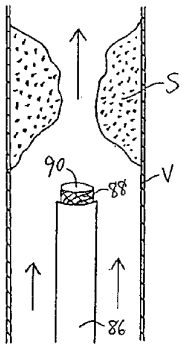

FIG 4A

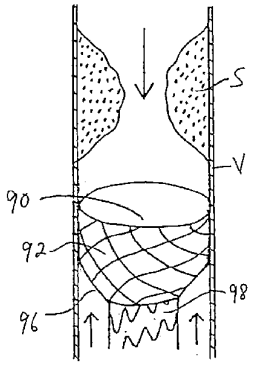

FIG.4B

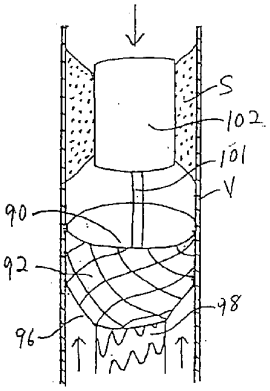

FIG. 4C

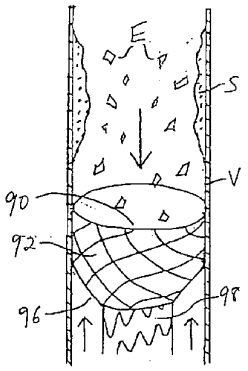

FIG. 4D

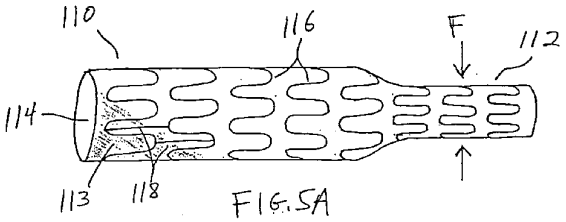

FIG. 5A

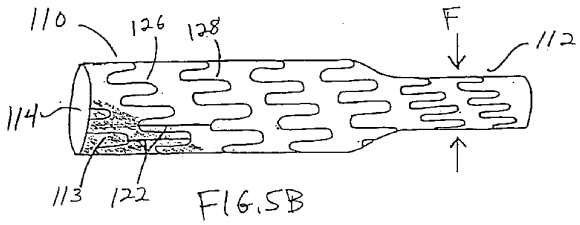

FIG. 5B

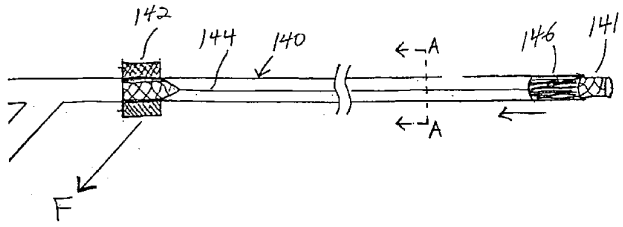

FIG. 6A

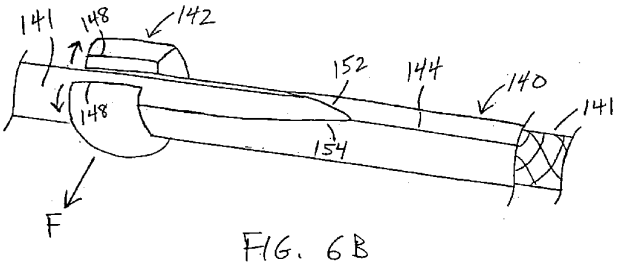

FIG. 6B

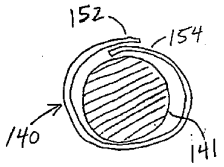

FIG. 6C

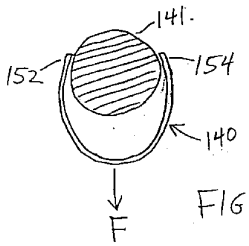

FIG. 6D

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(71) Applicant: ARTERIA MEDICAL SCIENCE, INC. [US/US]; The Presidio, Old Army Headquarters, Building 220, Suite 120, P.O. Box 29450, San Francisco, CA 94129 (US).

(72) Inventor: HOGENDIJK, Michael; 501 Forest Avenue #904, Palo Alto, CA 94301 (US).

(74) Agent: PISANO, Nicola, A.; Luce, Forward, Hamilton & Scripps LLP, 11988 El Camino Real, Suite 200, San Diego, CA 92130 (US).

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Declarations under Rule 4.17:
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for all designations*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations*

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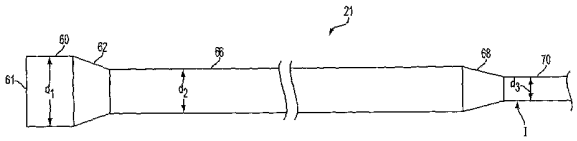
(54) Title: CATHETER HAVING RADIALLY EXPANDABLE MAIN BODY



(57) Abstract: Apparatus for occluding a vessel and enhancing blood flow within a catheter (21) are provided, wherein a catheter comprises a multi-section self-expanding wire weave forming a radially expandable body (46) and an occlusive distal section (60), covered with an outer sheath (22). Methods of using the apparatus of the present invention to remove emboli also are provided.

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(71) Applicant: ARTERIA MEDICAL SCIENCE, INC. [US/US]; The Presidio, Old Army Headquarters, Building 220, Suite 120, P.O. Box 29450, San Francisco, CA 94129 (US).

(72) Inventor: HOGENDIJK, Michael; 501 Forest Avenue #904, Palo Alto, CA 94301 (US).

(74) Agent: PISANO, Nicola, A.; Luce, Forward, Hamilton & Scripps LLP, 11988 El Camino Real, Suite 200, San Diego, CA 92130 (US).

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— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations*

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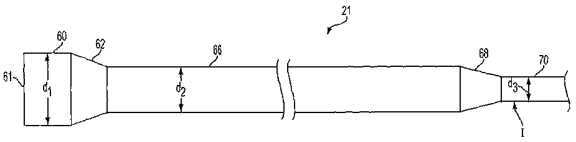
(54) Title: CATHETER HAVING RADIALLY EXPANDABLE MAIN BODY



(57) Abstract: Apparatus for occluding a vessel and enhancing blood flow within a catheter (21) are provided, wherein a catheter comprises a multi-section self-expanding wire weave forming a radially expandable body (46) and an occlusive distal section (60), covered with an outer sheath (22). Methods of using the apparatus of the present invention to remove emboli also are provided.

WO 2003/009880 A3

CATHETER HAVING RADIALLY EXPANDABLE MAIN BODY

Reference to Related Applications

The present application is a continuation-in-part of U.S. patent application Serial No. 09/418,727, filed October 15, 1999, which is a continuation-in-part of U.S. patent application Serial No. 09/333,074, filed June 14, 1999, which is a continuation-in-part of International Application PCT/US99/05469, filed March 12, 1999.

Field Of The Invention

The present invention relates to apparatus and methods for protecting against embolization during vascular interventions and improving flow characteristics within a catheter. More particularly, the apparatus and methods of the present invention facilitate blood flow within a catheter by providing a catheter having a radially expandable main body section.

Background Of The Invention

Catheters are commonly manufactured using materials that do not substantially change in cross-sectional area. It is highly desirable that the initial cross-sectional catheter area be relatively small compared to the vasculature for patient comfort and ease of transluminal guidance. However, catheters in which the working diameters remain relatively small have several disadvantages during interventional procedures.

A primary disadvantage of a small cross-sectional catheter area is increased flow resistance within the catheter. A high volume of blood flow being forced through a relatively small lumen may cause damage to blood cells. During interventional procedures involving the removal of emboli, the flow may be further constrained when aspirating large emboli in addition to blood. It therefore would be advantageous to provide a catheter having a small delivery cross-sectional area for transluminal insertion, but which is capable of expanding to a larger cross-sectional area, thus reducing flow resistance within the catheter.

Heretofore, no reliable expandable catheters have been available. U.S. Patent No. 5,102,401 to Lambert et al. describes a catheter comprising a thermoplastic elastomeric hydrophilic polyurethane coated on at least the outside surface with a hydrophobic polymer. The catheter expands to a larger lumen size in about 3 to 15 minutes when contacted with an aqueous liquid. Additional publications have further discussed catheters which soften upon being raised to a temperature approaching body temperature.

There are several drawbacks associated with

such previously known expandable catheters. Such catheters can soften when deployed, resulting in kinking or deformation of the proximal section of the catheter, thereby cutting off flow. Additionally, such catheters require a wait of up to several minutes for the desired expansion to occur. Accordingly, there remains a need for a structurally durable, rapidly expandable catheter.

Previously-known apparatus and methods are known that employ a mechanically expandable occlusive element disposed at the distal end of a catheter. Commonly assigned U.S. Patent No. 6,206,868 to Parodi discloses an occlusive element comprising a self-expanding wire mesh basket covered with an elastomeric polymer coating. The catheter is initially surrounded by a movable sheath, and is inserted transluminally with the sheath at a distalmost position. The sheath is retracted proximally to cause the basket to deploy, and the basket is again collapsed within the sheath by moving the sheath to its distalmost position.

The occlusive basket described in the Parodi patent is advantageous because it provides a rapidly expandable basket that is substantially flush with the vessel wall to enhance emboli removal. However, emboli then may be funneled into a relatively small cross-sectional area lumen that extends from the site of the stenosis to the vascular entry site. For many procedures, this distance may comprise the vast majority of the overall catheter length. Accordingly, blood flow is potentially constrained throughout the majority of the catheter.

In view of these drawbacks of previously known catheters, it would be desirable to provide apparatus and methods for radially varying the size of

a catheter so that the catheter can be maneuvered within the body at a contracted delivery diameter and then self-expands to a larger diameter to facilitate blood flow.

It also would be desirable to provide apparatus and methods for enhancing the flow of blood and emboli within a catheter by expanding the cross-sectional area of the catheter that extends from the site of the stenosis to the vascular entry site.

It still further would be desirable to provide apparatus and methods for rapidly expanding the cross-sectional area of a catheter without relying on chemical or thermal transformations.

It still further would be desirable to provide apparatus and methods for an expandable catheter whereby the structural integrity is not compromised upon expansion.

It still further would be desirable to provide apparatus and methods for efficiently removing emboli by means of an occlusive member that is substantially flush with the vessel wall.

Summary Of The Invention

In view of the foregoing, it is an object of the present invention to provide apparatus and methods for radially varying the size of a catheter so that the catheter can be maneuvered within the body at a contracted delivery diameter and then self-expands to a larger diameter in situ to facilitate blood flow.

It is another object of the present invention to provide apparatus and methods for enhancing the flow of blood and emboli within a catheter by expanding the cross-sectional area of the catheter that extends from the site of the stenosis to the vascular entry site.

It is another object of the present invention to provide apparatus and methods for rapidly self-expanding the cross-sectional area of a catheter without relying on chemical or thermal transformations.

It is yet another object of the present invention to provide apparatus and methods for an expandable catheter whereby the structural integrity is not compromised upon expansion.

It is another object of the present invention to provide apparatus and methods for efficiently removing emboli by means of an occlusive member that is substantially flush with the vessel wall.

These and other objects of the present invention are accomplished by providing apparatus and methods suitable for removing emboli and facilitating blood flow within a catheter. The apparatus preferably comprises a catheter having a wire weave configuration, an elastomeric polymer coating covering the weave to provide a blood impermeable membrane, and an outer sheath covering the catheter in a contracted state. The catheter preferably comprises an occlusive distal section, a radially expanding main body, and a fixed diameter proximal section that passes through the vascular entry site.

In a preferred method, the catheter is advanced through the femoral artery and the distal end is positioned proximal to a lesion. As the outer sheath covering the catheter is retracted proximally, the occlusive distal section expands to a predetermined shape to form an occlusive seal against the vessel wall. As the outer sheath is further retracted, the main body of the catheter expands radially to a larger diameter. The outer sheath is further retracted proximally toward the vascular entry site, e.g., the

arteriotomy.

The occlusive distal section occludes antegrade flow, and retrograde flow may be induced at the site of the stenosis, e.g., via negative pressure in a venous return line. An interventional procedure, such as angioplasty, stenting or atherectomy, then may be performed to treat the lesion. Emboli generated during the procedure are directed via the retrograde flow into the enlarged lumen of the catheter for subsequent removal.

Brief Description Of The Drawings

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments, in which:

FIG. 1 is a side view of apparatus constructed in accordance with the present invention in a collapsed delivery state;

FIGS. 2A-2C are schematic illustrations of the expandable features of the catheter;

FIG. 3 is a side view of a catheter constructed in accordance with the present invention in a fully deployed state;

FIGS. 4A-4D depict method steps of using the catheter of the present invention;

FIGS. 5A-5B illustrate alternative configurations of the expandable body of the catheter; and

FIGS. 6A-6D describe a mechanism for enabling proximal retraction of the outer sheath of the present invention.

Detailed Description Of The Invention

Referring to FIG. 1, embolic protection apparatus 20 constructed in accordance with principles of the present invention is described. Apparatus 20 comprises catheter 21, outer sheath 22, venous return line 32, tubing 29 and optional blood filter 30.

Catheter 21 comprises lumen 40 that communicates with hemostatic port 23, e.g., a Touhy-Borst connector and blood outlet port 28. Tubing 29 couples blood outlet port 28 to filter 30 and blood inlet port 31 of venous return line 32.

Outer sheath 22 preferably comprises clip 25, longitudinal slit 27 and solid distal section 35. Clip 25 is affixed to the proximal end of outer sheath 22 and may engage catheter 21 in a locked state, as shown in FIG. 1, or may disengage from catheter 21 when a force is applied. As described hereinbelow, longitudinal slit 27 permits outer sheath 22 to disengage from catheter 21, to allow proximal retraction of outer sheath 22 without interfering with blood outlet port 28 or hemostatic port 23.

Hemostatic port 23 and lumen 40 are sized to permit interventional devices, such as balloon angioplasty catheters, atherectomy devices and stent delivery systems, to be advanced through lumen 40 to the site of the occlusion.

Venous return line 32 includes hemostatic port 33, blood inlet port 31 and a lumen that communicates with ports 33 and 31 and tip 34. Venous return line 32 may be constructed in a manner per se known for venous introducer catheters. Tubing 29 may comprise a suitable length of a biocompatible material, such as silicone. Alternatively, tubing 29 may be omitted and blood outlet port 28 of catheter 21 and

blood inlet port 31 of venous return line 32 may be lengthened to engage either end of filter 30 or each other.

Referring to FIGS. 2, the expandable features of catheter 21 are described in greater detail. FIG. 2A depicts catheter 21 having lumen 40 in a contracted state within outer sheath 22. The device may be transluminally inserted and positioned within a vessel V in the contracted state. The distal section of catheter 21 may be constructed in an expandable wire weave configuration. In a preferred embodiment, the wire weave comprises a shape-memory retaining material, for example, a Nickel Titanium alloy (commonly known in the art as Nitinol).

The use of Nitinol generally requires the setting of a custom shape in a piece of Nitinol, e.g., by constraining the Nitinol element on a mandrel or fixture in the desired shape, and then applying an appropriate heat treatments, which are per se known.

Catheter 21 preferably is enclosed by elastomeric polymer 45, such as latex, polyurethane or polyisoprene. The shape of catheter 21 is initially constrained by outer sheath 22. As outer sheath 22 is retracted proximally, wires 43 and lumen 40 expand radially and may expand linearly to form occlusive distal section 42 having mouth 52, as shown in FIG. 2B. Elastomeric polymer 45 stretches to conform to the expanded shape. The predetermined configuration preferably comprises angled taper 44 and hoop 47.

The radial expansion of occlusive distal section 42 is such that its outer diameter is substantially flush with the intima of vessel V to occlude antegrade flow. Additionally, the surface contact between occlusive distal section 42 and vessel

V may effectively anchor the device.

Angled taper 44 facilitates direction of blood and emboli from mouth 52 into main body 46 of catheter 21. Additionally, angled taper 44 permits outer sheath 22 to slide distally over occlusive distal section 42 to effectively collapse that section within the sheath.

Hoop 47 may be used to separate occlusive distal section 42 from main body 46, as the two sections preferably have distinct expanded diameters. Main body 46 comprises a wire configuration that is initially compressed circumferentially within outer sheath 22. As outer sheath 22 is further retracted proximally, main body 46 expands radially within vessel V, as shown in FIG. 2C. Wires 48 expand radially to a predetermined shape that may be established, for example, by heat treating a shape-memory alloy as described hereinabove. Exemplary wire configurations for main body 46 are described in FIGS. 5 hereinbelow.

Referring now to FIG. 3, a schematic side view of catheter 21 is depicted in a fully deployed state. Catheter 21 comprises occlusive distal section 60, main body 66, proximal section 70, and angled tapers 62 and 68. Occlusive distal section 60 and main body 66 comprise expanded diameters d_1 and d_2, respectively, while proximal section 70 comprises transluminal insertion diameter d_3.

Occlusive distal section 60 and main body 66 are initially collapsed within outer sheath 22 such that their contracted diameters are substantially equal to the transluminal insertion diameter d_3 of proximal section 70. Catheter 21 then may be percutaneously and transluminally inserted into the body and maneuvered

within the vasculature at diameter d_3 until deployed, as depicted in FIGS. 2.

In the deployed state, d_1 is sized to occlude blood flow in the targeted vessel (other than through mouth 61). Diameter d_1 may expand to occlude flow in a range of vessels. Occlusive distal section 60 facilitates removal of large emboli via mouth 61. Angled taper 62 assists in directing blood and emboli from occlusive distal section 60 into main body 66. Blood and emboli then are directed proximally at transport diameter d_3.

Advantageously, the enlarged lumen provided by main body 66 transports blood from a location near the lesion to a location slightly distal to vascular entry site I, a distance that preferably spans the majority of the overall length of catheter 21. Accordingly, flow resistance may be reduced throughout the majority of the catheter.

Angled taper 68 funnels blood from main body 66 into proximal section 70. Proximal section 70 preferably remains fixed at transluminal insertion diameter d_3 and extends from blood outlet port 28 to a location slightly distal to vascular entry site I.

Referring to FIGS. 4A-4D, use of apparatus in accordance with the present invention is described. In FIGS. 4, lesion S is located within a vessel V of the body. In a first step, catheter 88, initially compressed within outer sheath 86, is inserted either percutaneously and transluminally or via a surgical cut-down, to a position proximal to lesion S, as shown in FIG. 4A. As described hereinabove, outer sheath 86 then is retracted proximally to cause occlusive distal section 92 to deploy, as shown in FIG. 4B, and further

retracted proximally to radially expand main body 98.

Venous return line 32 then may be introduced into the patient's femoral vein, either percutaneously or via a surgical cut-down. Filter 30 then is coupled between blood outlet port 28 of catheter 21 and blood inlet port 31 of venous return line 32 using tubing 29, and any air is removed from the line. Once this circuit is closed, negative pressure in venous return line 32 during diastole will establish a low rate continuous flow of blood through lumen 90 of catheter 21. As shown in FIG. 4B, the deployment of occlusive distal section 92 occludes antegrade flown in vessel **V**, while the negative pressure through lumen 90, e.g., from venous return line 32, induces retrograde flow at the site of the lesion.

This low rate continuous flow due to the difference between venous pressure and arterial pressure will continue throughout the interventional procedure. Specifically, blood passes through lumen 90 and blood outlet port 28 of catheter 21, through biocompatible tubing 29 to filter 30, and into blood inlet port 31 of venous return line 32, where it is reperfused into the remote vein. Continuous blood flow (except during inflation of any dilatation instruments) with reperfusion in accordance with the present invention provides efficient embolic removal with significantly reduced blood loss.

Referring to FIG. 4C, with occlusive distal section 92 deployed and retrograde flow established in vessel **V**, an interventional procedure to treat lesion **S** may be performed. The procedure may be any commonly known in the art. For example, balloon angioplasty may be applied whereby conventional angioplasty balloon catheter 101 having balloon 102 may be loaded through

hemostatic port 23 and lumen 90, then positioned within lesion **S**. Hemostatic port 23 then is closed, and balloon 102 is inflated to treat lesion **S**. Balloon 102 then is deflated upon satisfactory removal or disruption of lesion **S**.

Referring to FIG. 4D, emboli **E** generated during the procedure are directed into lumen 90 via the established retrograde flow. Angled taper 96 funnels blood and emboli **E** into main body 98. Blood and emboli **E** travel proximally within catheter 21, and emboli **E** may be subsequently removed via filter 30.

Upon completion, outer sheath 86 may be advanced distally along the length of catheter 21 to collapse main body 98 and occlusive distal section 92 within the sheath, which in turn causes antegrade flow to become re-established in vessel **V**. Catheter 21 then may be retracted transluminally and the apparatus may be removed from the patient's vessel.

Referring to FIGS. 5, alternative configurations of the radially expanding main body in accordance with the present invention are described. In FIG. 5A, a hoop configuration is shown wherein main body 110 of catheter 21 comprises several individual hoops 116. Individual hoops 116 are designed such that they may be compressed circumferentially by a compressive force **F**, e.g., the force provided by outer sheath 22, as depicted in region 112. When compressive force **F** is removed, hoops 116 expand to a larger, predetermined diameter. In a preferred embodiment, hoops 116 are manufactured from a shape-memory material, e.g, Nitinol, according to methods described hereinabove.

Individual hoops 116 preferably are enclosed within elastomeric polymer coating 113 to form an expandable, blood impermeable membrane. Individual hoops 116 may be connected to adjacent hoops via linkages 118 for additional structural stability.

Alternatively, main body 110 may comprise a plurality of compressible, spiral-shaped wires. As shown in FIG. 5B, wires 126 and 128 are angled such that they form long, continuous spirals along the length of main body 110. The compressible, spiral-shaped wires preferably comprise a shape memory material and may be coated with elastomeric polymer 113. Linkages 122 may be used to provide additional support between adjacent spirals.

Referring now to FIGS. 6, a mechanism for allowing proximal retraction of outer sheath 140 is described. Outer sheath 140 comprises clip 142, longitudinal slit 144 and solid distal section 146, as shown in FIG. 6A.

Clip 142 is sized to engage catheter 141 in a locked state, as shown in FIG. 6B. Clip 142 preferably comprises a compliant rubber-like material that may deform when a force **F** is applied in the direction indicated, i.e., a manual force applied by the physician. Walls 148 of clip 142 may part to allow clip 142 to disengage from catheter 141.

Longitudinal slit 144 of outer sheath 140 preferably comprises flaps 152 and 154. In a contracted state, flaps 152 and 154 overlap to enclose catheter 141, as shown in FIG. 6C from a sectional view through section line A--A of FIG. 6A. As a force **F** is applied, flaps 152 and 154 disengage from catheter 141, as shown in FIG. 6D from a sectional view through section line A--A.

Solid distal section 146 guides outer sheath 140 as it is further retracted proximally. When the procedure is completed, outer sheath 140 is advanced distally such that flaps 152 and 154 once again overlap. In this overlapping state, outer sheath 140 retracts catheter 141 within the sheath as the sheath is advanced distally. Clip 142 then may re-engage catheter 141.

While preferred illustrative embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made therein without departing from the invention. The appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

What Is Claimed Is:

1. Apparatus suitable for removing emboli from a vessel, the apparatus comprising a catheter having a proximal section, an occlusive distal section, a main body extending therebetween, and a lumen extending therethrough, and an outer sheath, the outer sheath disposed to slide longitudinally along the catheter, the improvement comprising that the main body has a contracted delivery diameter when disposed within the outer sheath and a radially expanded deployed diameter when deployed from the outer sheath.

2. The apparatus of claim 1 wherein the proximal section comprises a fixed diameter.

3. The apparatus of claim 1 wherein the occlusive distal section comprises a contracted state and an expanded state suitable for occluding flow in a vessel.

4. The apparatus of claim 3 wherein the occlusive distal section further comprises a wire weave configuration that forms a predetermined shape in the expanded state.

5. The apparatus of claim 4 wherein the predetermined shape of the occlusive distal section, when deployed, is substantially flush with the vessel wall at a distal portion and tapers in proximally to connect to the main body of the catheter.

6. The apparatus of claim 4 wherein the occlusive distal section comprises Nitinol.

7. The apparatus of claim 1 wherein the main body comprises a plurality of individually compressible hoops.

8. The apparatus of claim 7 wherein the main body consists of a nickel-titanium alloy.

9. The apparatus of claim 7 wherein the individually compressible hoops are enclosed within an elastomeric polymer coating.

10. The apparatus of claim 7 further comprising a plurality of linkages connecting the individually compressible hoops.

11. The apparatus of claim 1 wherein the main body comprises a spiral configuration having a plurality of compressible spiral-shaped wires.

12. The apparatus of claim 11 wherein the main body consists of a nickel-titanium alloy.

13. The apparatus of claim 11 wherein the compressible spiral-shaped wires are enclosed within an elastomeric polymer coating.

14. The apparatus of claim 11 further comprising a plurality of linkages connecting the compressible spiral-shaped wires.

15. The apparatus of claim 1 wherein the main body spans a greater distance than the proximal section.

16. The apparatus of claim 1 wherein the diameter of the main body in an expanded state is larger than the diameter of the proximal section.

17. The apparatus of claim 1 wherein the outer sheath is positioned in a distalmost position to compress the main body and occlusive distal section within the outer sheath.

18. A method for enhancing flow within a catheter, the method comprising:

providing a catheter in a contracted state, wherein the catheter comprises a proximal section, an occlusive distal section, a main body extending therebetween, and a lumen extending therethrough;

retracting an outer sheath proximally to deploy the occlusive distal section; and

further retracting the outer sheath proximally to cause radial expansion of the main body.

19. The method of claim 18 further comprising:

performing an interventional procedure; and

aspirating emboli generated during the interventional procedure into the lumen of the catheter.

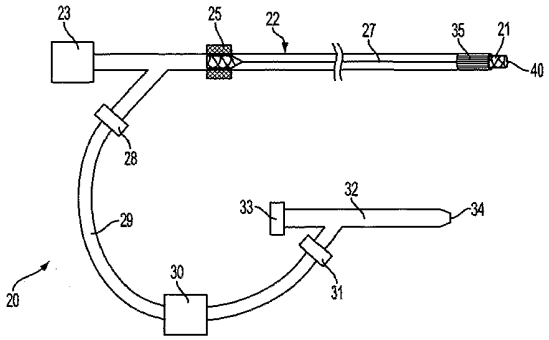


FIG. 1

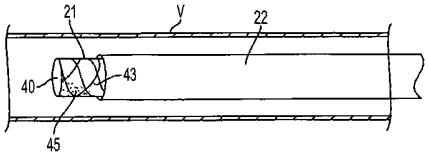


FIG. 2A

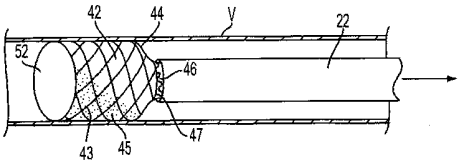


FIG. 2B

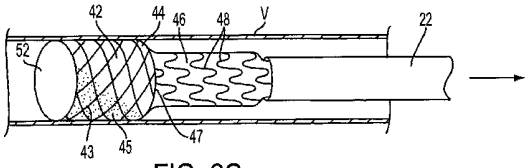


FIG. 2C

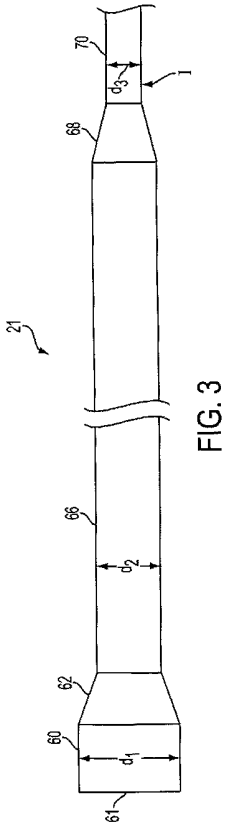


FIG. 3

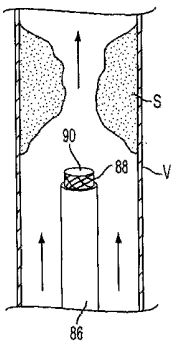


FIG. 4A

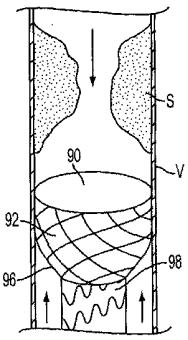


FIG. 4B

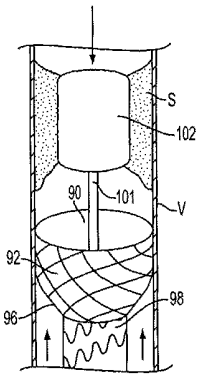


FIG. 4C

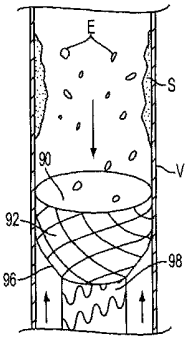


FIG. 4D

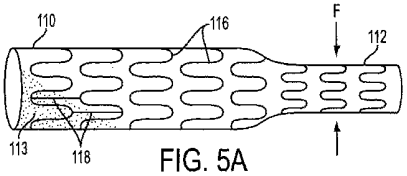


FIG. 5A

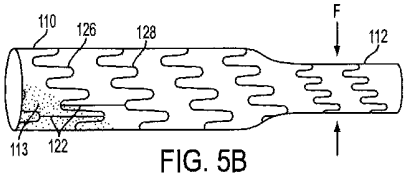


FIG. 5B

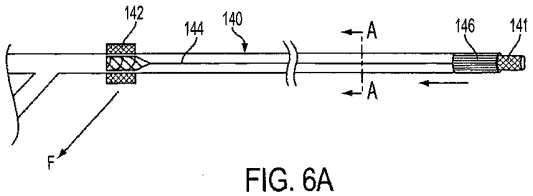


FIG. 6A

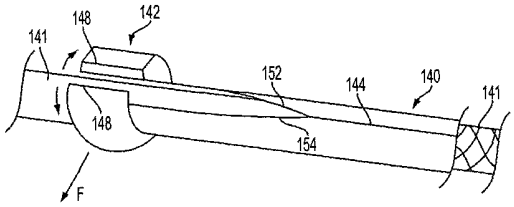


FIG. 6B

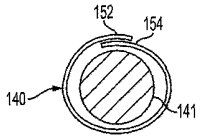


FIG. 6C

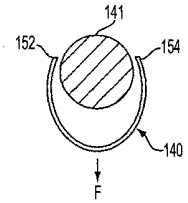


FIG. 6D

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/22822

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61M 29/00
US CL : 606/193, 198, 200
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/193, 198, 200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,064,435 A (PORTER) 12 November 1991, figures 1-5.	1-19

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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(72)発明者 ホーゲンダーク, マイケル
アメリカ合衆国 カリフォルニア ９４３０１, パロ アルト, フォレスト アベニュー ５０１ ナンバー９０４

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