

(19) 日本国特許庁(JP)

(12) 公表特許公報(A)

(11) 特許出願公表番号

特表2004-509653

(P2004-509653A)

(43) 公表日 平成16年4月2日(2004.4.2)

(51) Int.Cl.⁷

A61M 29/02

A61M 1/00

F I

A61M 29/02

A61M 1/00 550

テーマコード (参考)

4C077

4C167

審査請求 未請求 予備審査請求 有 (全 99 頁)

(21) 出願番号 特願2001-556527 (P2001-556527)
(86) (22) 出願日 平成13年1月30日 (2001.1.30)
(85) 翻訳文提出日 平成14年7月31日 (2002.7.31)
(86) 国際出願番号 PCT/US2001/003001
(87) 国際公開番号 W02001/056629
(87) 国際公開日 平成13年8月9日 (2001.8.9)
(31) 優先権主張番号 60/180, 131
(32) 優先日 平成12年2月3日 (2000.2.3)
(33) 優先権主張国 米国 (US)
(31) 優先権主張番号 60/188, 002
(32) 優先日 平成12年3月9日 (2000.3.9)
(33) 優先権主張国 米国 (US)
(31) 優先権主張番号 09/733, 752
(32) 優先日 平成12年12月8日 (2000.12.8)
(33) 優先権主張国 米国 (US)

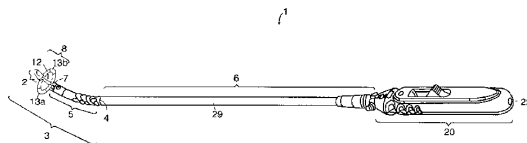
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(54) 【発明の名称】 排出を容易とするステント

(57) 【要約】

本発明による前立腺用ステントは、本体と保持部材とを具備している。本体は、先端終端部と、基端部と、内部を通して延在するとともに本体を通過しての流体排出を可能とする管腔と、を有している。本体は、外部括約筋の通常動作を可能とし得るよう先端終端部を外部括約筋よりも基端側に位置させた状態でもって、尿路の前立腺部分内に実質的に配置され得るようなサイズとされている。保持部材は、本体の基端部から突出している。保持部材は、前立腺用ステントが尿路内を通過し得るような第1状態へと縮小することができ、また、膀胱内に配置されたときには、本体を前立腺部分内に実質的に位置決めし得るよう、第2状態へと拡張可能とされている。



【特許請求の範囲】

【請求項 1】

前立腺用ステントであって、

(a) 先端終端部と、基端部と、内部を通して延在する管腔と、を有するとともに、前記先端終端部を外部括約筋よりも基端側に位置させた状態でもって尿路の前立腺部分内に実質的に配置され得るようなサイズとされた本体と；

(b) 該本体の前記基端部から突出するとともに、縮小状態と拡張状態とが可能とされている保持部材と；

を具備することを特徴とする前立腺用ステント。

【請求項 2】

請求項 1 記載のデバイスにおいて、

前記保持部材の基端部が、テーパ形状とされていることを特徴とするデバイス。

【請求項 3】

請求項 1 記載のデバイスにおいて、

前記保持部材が、前記本体と一体的に形成されていることを特徴とするデバイス。

【請求項 4】

請求項 1 記載のデバイスにおいて、

前記保持部材が、前記拡張状態となるように付勢されていることを特徴とするデバイス。

【請求項 5】

請求項 1 記載のデバイスにおいて、

前記保持部材が、前記拡張状態となるように付勢されている少なくとも 2 つのアームを有していることを特徴とするデバイス。

【請求項 6】

請求項 1 記載のデバイスにおいて、

前記本体が、前記管腔と連通している少なくとも 1 つの側部開口を有していることを特徴とするデバイス。

【請求項 7】

請求項 1 記載のデバイスにおいて、

前記本体が、前記尿路の前記前立腺部分内における前記本体の保持を補助し得るよう、少なくとも 1 つの突出部分を有していることを特徴とするデバイス。

【請求項 8】

請求項 1 記載のデバイスにおいて、

前記本体が、前記尿路内に配置されたときに前記管腔を維持し得るようなフレキシブルかつソフトな材料を備えていることを特徴とするデバイス。

【請求項 9】

請求項 1 記載のデバイスにおいて、

さらに、前記医療デバイスから前記尿路を通して延在するとともに外側開口の外部において終端しており、引っ張ることによって前記尿路からの前記医療デバイスの取外しを可能とするための、縫糸を具備していることを特徴とするデバイス。

【請求項 10】

前立腺処置後において膀胱から前立腺を通しての流体排出を行うための前立腺用ステントーカテーテルシステムであって、

(a) 先端終端部と基端部と内部を通して延在する管腔とを有するとともに前記先端終端部を外部括約筋よりも基端側に位置させた状態でもって尿路の前立腺部分内に実質的に配置され得るようなサイズとされた本体を備えている、ステントと；

(b) 患者の体外に配置される先端部と前記ステントの前記先端終端部に対して着脱可能に連結される基端部と内部を通して延在する管腔とを有した長尺本体を備えている、連結セグメントと；

を具備することを特徴とする前立腺用ステントーカテーテルシステム。

【請求項 11】

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請求項 10 記載の前立腺用ステントーカテーテルシステムにおいて、前記ステントが、さらに、前記本体の前記基端部から突出するとともに前記尿路の前記前立腺部分内に実質的に前記本体を保持し得る保持部材を備えていることを特徴とする前立腺用ステントーカテーテルシステム。

【請求項 12】

請求項 10 記載の前立腺用ステントーカテーテルシステムにおいて、前記ステントが、さらに、前記本体の前記基端部から突出するとともに縮小状態と拡張状態とが可能とされている保持部材を備えていることを特徴とする前立腺用ステントーカテーテルシステム。

【請求項 13】

請求項 12 記載の前立腺用ステントーカテーテルシステムにおいて、さらに、
(a) 前記前立腺用ステントーカテーテルシステムによってスライド可能に受領され得るとともに、挿入端と外部端とを有し、さらに、前記挿入端が前記ステントの前記基端部に対して当接することができかつ前記外部端が患者の体外に位置することができるようなサイズとされた押込デバイスと；
(b) 前記連結セグメントの前記先端部に対して固定されるとともに、流体排出を可能とする少なくとも 1 つの開口と、前記押込デバイスに対して取り付けられているとともに外科医が前記連結セグメントの前記管腔内でのおよび前記ステントの前記管腔内での前記押込デバイスの位置を制御できるようにするための機構と、を備えているハンドルと；
を具備していることを特徴とする前立腺用ステントーカテーテルシステム。

【請求項 14】

請求項 13 記載のハンドルにおいて、
(a) 前記機構を第 1 位置に移動させることにより、前記押込デバイスを基端側に突出させることができ、これにより、前記ステントの前記保持部材を前記縮小状態とすることができ、
(b) 前記機構を第 2 位置に移動させることにより、前記押込デバイスを引っ込めることができ、これにより、前記ステントの前記保持部材を前記拡張状態とすることができ、
(c) 前記機構を第 3 位置に移動させることにより、前記押込デバイスを引っ込めることができ、これにより、前記押込デバイスと前記ステントの前記基端部との間の当接を解除することができる、
ようになっていることを特徴とするハンドル。

【請求項 15】

請求項 13 記載の押込デバイスにおいて、前記挿入端が、直線状であることを特徴とする押込デバイス。

【請求項 16】

請求項 13 記載の押込デバイスにおいて、前記挿入端が、湾曲していることを特徴とする押込デバイス。

【請求項 17】

請求項 10 記載の前立腺用ステントーカテーテルシステムにおいて、前記ステントが、さらに、自己拡張性かつ生体適合性材料と、大きなポアを有したメッシュ構成と、を備えていることを特徴とする前立腺用ステントーカテーテルシステム。

【請求項 18】

請求項 17 記載の前立腺用ステントーカテーテルシステムにおいて、さらに、
(a) 前記前立腺用ステントーカテーテルシステムによってスライド可能に受領され得るとともに、挿入端と外部端とを有し、前記挿入端が前記ステントの前記基端部に対して係合することができ、さらに、前記挿入端が前記ステントの前記基端部に対して係合することができかつ前記外部端が患者の体外に位置することができるようなサイズとされた押込デバイスと；
(b) 前記連結セグメントの前記先端部に対して固定されるとともに、流体排出を可能とする少なくとも 1 つの開口と、前記押込デバイスに対して取り付けられているとともに外

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科医が前記連結セグメントの前記管腔内でのおよび前記ステントの前記管腔内での前記押込デバイスの位置を制御できるようにするための機構と、を備えているハンドルと；を具備し、

(i) 前記機構を第1位置に移動させることにより、前記押込デバイスを基端側に突出させることができ、これにより、前記ステントを解放することができ、

(ii) 前記機構を第2位置に移動させることにより、前記押込デバイスを引っ込めることができ、これにより、前記ステントの前記管腔内から前記押込デバイスを取り外すことができる、ようになっていることを特徴とする前立腺用ステントーカテーテルシステム。

【請求項19】

前立腺用ステントーカテーテルシステムの配置方法であって、

(a) (i) 先端終端部と基端部と内部を通して延在する管腔とを有するとともに前記先端終端部を外部括約筋よりも基端側に位置させた状態でもって尿路の前立腺部分内に実質的に配置され得るようなサイズとされた本体を備えている、ステントと；

(ii) 患者の体外に配置される先端部と前記ステントの前記先端終端部に対して着脱可能に連結される基端部と内部を通して延在する管腔とを有した長尺本体を備えている、連結セグメントと；

を具備してなる前立腺用ステントーカテーテルシステムを準備し；

(b) 該前立腺用ステントーカテーテルシステムを、患者の尿路内に挿入し；

(c) 前記ステントを、前記尿路の前立腺部分内に実質的に配置し；

(d) 前記ステントを通してさらに前記連結セグメントを通してさらに患者の体外に配置された前記連結セグメントの前記先端部から流出する流体排出状況を観測し；

(e) 前記ステントと前記連結セグメントとの連結を解除し；

(f) 前記尿路および患者の体内から前記連結セグメントを完全に引き抜く；ことを特徴とする方法。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】

本出願は、2000年2月3日付けで出願された米国予備出願第60/180,131号および2000年3月9日付けで出願された米国予備出願第60/188,002号の優先権を主張するものである。

【0002】

本発明は、排出の容易化に関するものであり、より詳細には、患者の膀胱からの尿道を通しての流体排出を容易とすることに関するものである。

【0003】

【従来の技術および発明が解決しようとする課題】

前立腺とは、男性の排尿系において、膀胱の直下かつ尿道の周囲に配置された腺である。特に50代以上の男性において、いくらかの男性においては、疾病や感染のために、前立腺が肥大または膨化することがある。肥大した前立腺は、尿道を圧迫してしまい、不快感をもたらしたり、膀胱からの排出障害を引き起こしたりする。

【0004】

肥大した前立腺を治療するための公知方法の1つは、前立腺温熱療法である。この前立腺温熱療法においては、前立腺を体温以上へと加熱することによって、疾病組織を除去し、前立腺を標準サイズへと戻す。しかしながら、この治療の直後においては、治療によって誘起された治療トラウマのために、前立腺が、なおも肥大する。治療を受けた前立腺が元に戻って、膀胱からの排出を阻害しなくなるまでには、数週間を必要とする。

【0005】

【課題を解決するための手段】

本発明は、患者の膀胱からの流体排出をもたらすことに関するものである。本発明によるシステムおよび方法は、典型的には、例えば温熱治療といったような前立腺治療を患者が受けた後に、使用される。本発明によるシステムおよび方法は、尿排出カテーテルをイン

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サイテュで埋設デバイスへと変換する。このデバイスは、尿路の前立腺部分を開放状態に維持し、流体を通過させ得るとともに、患者の外部括約筋の通常動作を可能とする。このため、患者は、尿路の前立腺部分内の所定位置にデバイスが配置されている状況であるにもかかわらず、膀胱からの排尿の確保に関しての完全な通常的制御性を得ることができる。

【0006】

概して、ある見地においては、本発明は、前立腺用ステントに関するものである。この前立腺用ステントは、本体と保持部材とを具備している。本体は、先端終端部と、基端部と、内部を通過して延在するとともに本体を通過しての流体排出を可能とする管腔と、を有している。基端および先端という方向性に係わる用語は、参照ポイントを必要とする。本発明においては、方向性を決定する際の参照ポイントは、患者を中心とした座標である。そのため、基端という用語は、常に、患者の体内を向く向きを意味しており、先端という用語は、常に、患者の体外へと向かう向きを意味している。本体は、尿路の前立腺部分内に実質的に配置され得るようなサイズとされている。外部括約筋の通常動作を可能とし得るよう、先端終端部は、外部括約筋よりも基端側に位置される。保持部材は、本体の基端部から突出している。保持部材は、最初の時点においては、前立腺用ステントが尿路内を通過し得るような第1状態へと縮小される。また、保持部材は、膀胱内に配置されたときには、本体を前立腺部分内に実質的に位置決めし得るよう、第2状態へと拡張可能とされている。

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【0007】

本発明のこの見地における実施形態は、以下の特徴点を備えることができる。前立腺用ステントの保持部材は、患者の尿路内へのステントの挿入時に患者に対してのソフトさをもたらし得るよう、テーパ形状とすることができる。また、保持部材は、2つ以上の保持アームを有することができ、これら保持アームは、第2状態となるように付勢することができる。患者の尿路内への前立腺用ステントの挿入前および挿入時においては、保持部材は、第1状態とされる。保持部材は、患者の膀胱内において第2状態へと実質的に復帰し、これにより、前立腺用ステントの本体を、尿路の前立腺部分内に実質的に保持する（位置決めする）ためのアンカーとして機能する。前立腺用ステントの本体は、尿路の前立腺部分から管腔内への流体排出を可能とし得るよう、1つまたは複数の側部開口を有することができる。前立腺用ステントの変位防止を補助するために、本発明は、また、1つまたは複数の突出部分を有することができる。突出部分は、尿路の前立腺部分をなす壁に対して係合し得るよう構成されており、尿路内における前立腺用ステントの変位を制限する摩擦源となる。本体は、また、先端終端部に対して取り付けられた縫糸を備えることができる。縫糸は、本体から患者の外側開口までにわたって延在し得るよう十分に長いものである必要がある。前立腺用ステントは、縫糸を引っ張ることによって、患者の体内から容易に除去することができる。縫糸の端部は、ボールや、リングや、コイルや、完全に体外に延在しているあるいは外側開口内に位置している他の構造に対して連結することができる。縫糸の端部におけるボールやリングやコイルや他の構造の意図は、縫糸の端部の位置決めを容易とすることであり、患者自身がまたは医療技術者が位置決め縫糸を単に引っ張ることによるステントの取外しを容易とすることである。

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【0008】

他の見地においては、本発明は、膀胱から前立腺部分を通しての、患者の体内からの流体排出を行うための前立腺用ステントーカテーテルシステムに関するものである。前立腺用ステントーカテーテルシステムは、ステントと連結セグメントとを具備している。ステントは、先端終端部と基端部と内部を通過して延在する管腔とを有する本体を備えている。本体は、外部括約筋の通常動作を可能とし得るよう、先端終端部を外部括約筋よりも基端側に位置させた状態でもって尿路の前立腺部分内に実質的に配置され得るようなサイズとされている。連結セグメントは、先端部と基端部と管腔とを有した長尺本体を備えている。連結セグメントの基端部は、ステントの先端終端部に対して着脱可能に連結される。前立腺用ステントーカテーテルシステムは、患者の尿路内に挿入された後において、少なくとも

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も2つの動作モードを有している。第1モードにおいては、ステントと連結セグメントとが互いに連結されていて、膀胱からの流体排出が連続的に行われる。第2モードにおいては、連結セグメントが、インサイテュでステントから連結解除され、その後、連結セグメントは、患者の尿路から除去される。患者の体内からの連結セグメントの除去後には、患者の外部括約筋は、収縮することができ、外部括約筋は、通常的に動作することができる。このため、患者は、排尿に関しての完全な制御性を得ることができる。

【0009】

本発明のこの見地における実施形態は、以下の特徴点を備えることができる。前立腺用ステントーカテーテルシステムのステントは、本体から基端向きに突出する保持部材を備えることができる。前立腺用ステントーカテーテルシステムが適切に配置されたときには、保持部材は、患者の膀胱内に位置することとなる。ある実施形態においては、保持部材は、ステントの先端向き変位を防止するための膀胱内におけるアンカーとして機能する基端湾曲チップを備えている。他の実施形態においては、保持部材は、拡張状態となるように付勢されている少なくとも2つの保持アームを備えている。これら保持アームは、患者の尿路内への前立腺用ステントーカテーテルシステムの挿入前および挿入時には、縮小することができ縮小される。この実施形態における保持アームは、患者の膀胱内に配置されたときには拡張状態へと復帰し、これにより、前立腺用ステントの変位を防止するためのアンカーとして機能する。保持アームの拡張は、前立腺用ステントを患者の体内に配置した状態であっても、押込部材によって制御することができる。前立腺用ステントーカテーテルシステムのステントは、さらに、大きなポアを有したメッシュ構成を有した本体を備えることができる。大きなポアを有したメッシュは、例えばニッケルチタンベース合金と似たような、任意の生体適合性かつ自己拡張性材料から形成することができる。大きなポアを有したメッシュを備えた本体は、患者の前立腺に対して摩擦係合し、これにより、ステントの変位を防止するためのアンカーとして機能する。

【0010】

概して、なおも他の見地においては、本発明は、尿路内へと前立腺用ステントーカテーテルシステムを配置するための方法に関するものである。着脱可能に互いに連結されたステントと連結セグメントとを具備してなる前立腺用ステントーカテーテルシステムが、尿路内へと挿入される。例えば外科医のような医療技術者は、ステントの少なくとも一部が尿路の前立腺部分内へと実質的に配置されるまで、尿路を通して前立腺用ステントーカテーテルシステムを前進させる。適切に配置されたときには、ステントの少なくとも一部は、尿路の前立腺部分内に位置し、一方、連結セグメントは、外部括約筋を通してまた尿路の残部を通して延在するとともに患者の体外へと延在する。外科医は、連結セグメントの先端部を通しての尿または他の生体流体の排出を観測することによって、前立腺用ステントーカテーテルシステムの適切な配置を確認する。尿や血液といったような生体流体が前立腺用ステントーカテーテルシステムを通して排出される状況が、観測される。処置が、前立腺に対しての治療（例えば、手術）後に行われる場合には、医療技術者は、患者の前立腺が治療によって回復したかどうかをあるいは回復しつつあるかどうかを決定し、その後、連結セグメントとステントとを切り離し、患者の体内から連結セグメントの全体を引き抜く。ここで、ステントは、尿路の前立腺部分内に残留しており、膀胱出口障害を防止するとともに、患者の外部括約筋の通常動作（正常動作）を可能としつつも、尿路の前立腺部分を開放状態に維持して膀胱からの流体導出を可能としている。前立腺が完全に回復し流体排出障害というリスクがなくなったときには、ステントを除去することができる。埋設ステントの除去は、ステントに対して取り付けられた縫糸を引っ張ることによって行うことができる。縫糸は、典型的には、尿路から患者の体外へと残留したままの状態とされていたものである。あるいは、縫糸は、外部開口内の部分にまで残留させておくこともできる。よって、縫糸は、患者自身によってあるいは医師や看護師といったような医療技術者によって、容易に位置決めすることができる。

【0011】

【発明の実施の形態】

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本発明における上記のおよび他の目的や見地や特徴点や利点は、以下の説明によりおよび特許請求の範囲により、明瞭となるであろう。

【0012】

複数の図面にわたって、同じ参照符号は、同じ部材を示している。また、図面どうしは、必ずしも同一スケールで示されているわけではなく、本発明の原理を図示するために誇張されていることもある。

【0013】

本発明は、大まかには、膀胱の排出障害を救助することに関するものである。前立腺の治療後には、患者は、尿路の確保を得ることができる。本発明は、大まかには、尿路の確保処置に関するものであり、特に、男性の尿路の確保処置に関するものである。本発明においては、患者の尿路の前立腺部分内にステントを一時的に配置した状態であってさえも、患者の外部括約筋の通常動作は、可能とする（よって、膀胱からの通常の排尿を行うことができる）。

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【0014】

例えば前立腺温熱療法といったような障害前立腺の医療処置後においては、患者は、最新に処置された前立腺の回復とともに、前立腺出血を起こすことがある。そのような医療処置における他の場合においては、膀胱の排出障害が、なおもわずかに肥大しており、その後、前立腺が回復する。処置後においては、治療を行う医療技術者（例えば、外科医）や他の数人の医療技術者は、尿の量と前立腺の肥大とを観測し、患者の尿通路を開放状態に維持しようとする。患者の膀胱や前立腺からの生体流体を連続的に観測するために、患者の処置を行っている医療技術者は、そのような生体流体の一定でありかつ遮断されない排出を確保するために、患者の外部括約筋が締まらないようにする必要がある。一般に、処置に従事している医療技術者は、数時間にわたって患者の排尿系からの血液および尿の流通を観測するだけで良い。しかしながら、患者の前立腺の回復には数週間を必要とする。本発明の1つの目的は、患者の排尿系全体にわたって開放した通路を維持することによって前立腺治療後における所定期間にわたっての一定した排出を実現し得るような、また、膀胱から前立腺部分を通しての開放した尿通路をもたらしつつも、これと同時に、患者の外部括約筋の通常動作を可能としこれにより膀胱からの排尿に関しての完全に通常の制御性を患者が有するようにし得るような、デバイスやシステムや方法を提供することである。

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【0015】

図1および図2に示すように、本発明による前立腺用ステントーカテーテルシステム（1）は、前立腺用ステント（3）と、連結セグメント（6）と、を備えている。前立腺用ステント（3）は、本体（5）を有している。本体（5）は、例えばシリコンやナイロンやポリグリコール酸やステンレススチールといったような1つまたは複数の生体適合性材料から形成されているとともに、尿路の前立腺部分内に実質的に適合するようなサイズとされている。本体（5）は、基端部（7）と、先端終端部（4）と、基端部（7）から先端終端部（4）までにわたって延在し本体（5）を通過しての流体排出を可能とする管腔と、を有している。上述したように、基端という用語は、患者の体内を向く向きを意味しており、先端という用語は、患者の体外へと向かう向きを意味している。本体（5）は、ワイヤメッシュによって補強することができ、これにより、前立腺用ステント（3）の引っ張り強度を増大させ、管腔が潰れてしまう可能性を低減させることができる。図1および図2に示すような前立腺用ステント（3）は、さらに、保持部材（8）を備えている。保持部材（8）も、また、1つまたは複数の生体適合性材料から形成されている。この実施形態においては、保持部材（8）は、少なくとも2つの保持アーム（13a, 13b）を有している。膀胱からの流体排出を妨害することなく尿路の前立腺部分内に本体（5）をアンカー止めし得る限りにおいては、保持部材（8）としては、他の実施形態も可能である。保持部材の他のいくつかの構成例が、図3～図6に示されている。さらに他の可能ないくつかの保持部材形状には、傘状分岐や、ブタ尾状カール、がある。保持部材のすべての実施形態は、挿入を容易とし得るよう、縮小可能でなければならないまたは直線状とな

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り得なければならない。また、前立腺用ステントが、尿路の前立腺部分における前立腺用ステントの変位を防止するための他の手段を有している場合には（例えば、患者の前立腺に対して本体が摩擦的に係合する場合には）、保持部材は不要である。図1および図2に示すデバイスにおける実施形態においては、保持部材（8）は、基端チップ（2）を有している。基端チップ（2）においては、基端チップベース開口（9）から基端チップ開口（11）までにわたって延在する管腔が形成されている。保持部材（8）は、縮小可能なものであって、少なくとも2つの個別状態を有している。第1状態においては、保持部材（8）は、挿入を容易とし得るよう縮小状態とされる。第2状態においては、保持部材（8）は、拡張され、この拡張により、前立腺用ステント（3）が適切に配置された後において前立腺用ステント（3）が変位してしまわないように、前立腺用ステント（3）を固定することができる。前立腺用ステント（3）は、保持部材（8）が患者の膀胱内に配置されかつ本体（5）が尿路の実質的に前立腺部分内に配置されかつ先端終端部（4）が患者の外部括約筋の近傍に配置されることによって、男性の排尿系内に適切に配置される。前立腺用ステントーカテーテルシステム（1）の連結セグメント（6）は、基端部（28）と先端部（30）とを有した長尺本体（29）を備えている。基端部（28）から先端部（30）にわたっては、流体排出のための管腔が延在している。連結セグメント（6）の先端部（30）のところには、流体排出のための少なくとも1つの側部開口（26）が設けられている。

【0016】

前立腺用ステントーカテーテルシステム（1）の挿入に際しては、連結セグメント（6）の基端部（28）を、前立腺用ステント（3）の先端終端部（4）に対して着脱可能に連結する。前立腺用ステント（3）と連結セグメント（6）との連結により、本体（5）の基端部（7）から連結セグメント（6）の先端部（30）までにわたって延在するただ1つの管腔が形成される。前立腺用ステント（3）と連結セグメント（6）との連結にあたっては、ガイド（40）を使用する。ガイド（40）は、両端開放のチューブ状部材であって、連結セグメント（6）と本体（5）との双方よりもわずかに小さな直径を有している。ガイド（40）は、ガイド（40）の一部が連結セグメント（6）の管腔内に位置するようにして、かつ、ガイド（40）の残部が連結セグメント（6）の基端部（28）から外部に突出しているようにして、連結セグメント（6）の基端部（28）に対して固定される。その後、ガイド（40）の残部が、本体（5）の管腔内へと挿入される。これにより、前立腺用ステント（3）と連結セグメント（6）との間に、スリップフィット型シールが確立される。本体（5）の先端終端部（4）と連結セグメント（6）の基端部（28）とが、互いに着脱可能に連結される限りにおいては、他の様々な連結方式が可能である。例えば、他の実施形態においては、ガイド（40）は、前立腺用ステント（3）を適切に配置した後にインサイテュで取り外し得るものとされた縫糸によって、前立腺用ステント（3）に対して着脱可能に連結することができる。

【0017】

例えば温熱療法といったような障害前立腺の治療を行った後には、患者の前立腺は、典型的には、なおもわずかに肥大しており、出血することもある。膀胱の障害を防止するとともに、尿生成量と前立腺出血とを観測するために、外科医は、患者の尿路内へと前立腺用ステントーカテーテルシステム（1）を挿入することができる。この挿入は、基端チップ（2）が膀胱内に配置され、かつ、連結セグメント（6）が外部括約筋にわたって延在するような状況になるところまで、行われる。これにより、患者の膀胱から前立腺を通しての一定の流体排出が可能とされる。外科医が、患者の生体流体をそれ以上観測する必要がないと判断したときには、患者の膀胱からの一定の流体排出は、もはや不要である。しかしながら、わずかに肥大しているような最新に治療した前立腺に基づく膀胱の確保という潜在的なリスクを避けるために、外科医は、前立腺が完全に治癒するまでは、尿路の前立腺部分内に前立腺用ステント（3）を維持しようとする。患者の前立腺の治癒に数週間を要することを考慮して、また、患者が不便な思いをしないために、外科医は、連結セグメント（6）をただ単に引っ張ることによって、前立腺用ステントーカテーテルシステム（

1) から連結セグメント (6) を取り外し、前立腺用ステント (3) を所定位置に残すことができる。

【0018】

図1および図2に示す前立腺用ステントーカテーテルシステム (1) の実施形態は、さらに、押込デバイス (12) と、ハンドル (20) と、を備えている。押込デバイス (12) は、基端部 (36) と、先端部 (34) と、を有している。押込デバイス (12) の幅は、前立腺用ステント (3) の管腔内に適合し得るようなサイズとされている。一方、押込デバイス (12) の長さは、基端部 (36) が、前立腺用ステント (3) の基端チップ (2) に対して接触し得るとともに、先端部 (34) が、着脱可能に連結されている状態での連結セグメント (6) の先端部 (30) を超えて突出し得るような、サイズとされている。したがって、治療を行っている外科医は、前立腺用ステントーカテーテルシステム (1) が患者の体内に配置された後においては、押込デバイス (12) を使用することによって、前立腺用ステント (3) の基端チップ (2) に対して押込デバイス (12) を接触させることができる。押込デバイス (12) は、患者の解剖学的形状に対して適合し得るよう十分にフレキシブルでありかつ基端チップ (2) を本体 (5) から離間させ得るよう十分に剛直であるような、任意の材料から形成することができる。例えばステンレススチールやポリカーボネートといったような材料が、これら基準を満たす。押込デバイス (12) は、図7に示すように直線状のものとすることもあるいは図8に示すように湾曲したものとすることもでき、尿路の前立腺部分内への前立腺用ステント (3) の挿入および配置を補助することができる。押込デバイス (12) の全体にわたって、ガイドワイヤを受領し得る管腔が延在している。押込デバイス (12) の基端部 (36) のところには、基端チップ (2) と押込デバイス (12) との連結に際して使用するためのフランジ (32) が設けられている。このフランジ (32) は、また、押込デバイス (12) と基端チップ (12) との間の (意図していない) 時期尚早の分離を防止する。このフランジ (32) は、図9において最も明瞭に示されている。押込デバイスの他端である先端部 (34) には、ハンドル (20) 内に配置される機構 (24) が取り付けられている。この機構 (24) は、先端基端方向においてスライド式に移動可能とされている。機構 (24) が押込デバイス (12) に対して取り付けられていることにより、この機構 (24) の位置が、前立腺用ステントーカテーテルシステム (1) 内における押込デバイス (12) の位置を決定する。ハンドル (20) は、連結セグメントの先端部 (30) に対して取り付けられており、患者の体外に位置している。したがって、外科医は、治療時には、いつでも、押込デバイス (12) の位置を操作することができる。機構 (24) の他にも、ハンドル (20) は、前立腺用ステントーカテーテルシステム (1) からの流体排出のための少なくとも1つの開口 (22) を有している。

【0019】

前立腺用ステント (3) の図1および図2に示す実施形態は、本体 (5) の管腔と連通した一連の開口 (10, 14a, 14b, 14c, 14d) と、一連の突出節 (16a, 16b, 16c, 16d, 16e) と、を有している。これら特徴点は、図10～図12において最も明瞭に示されている。本体 (5) 上におけるこれら一連の開口 (10, 14a～14d) および／または一連の突出節 (16a～16e) は、前立腺用ステント (3) が変位してしまうという傾向を低減する。複数の突出節は、互いに平行なものとするとも、あるいは、さらに変位しにくくするために徐々に角度を大きくしたものとするとも、できる。この実施形態においては、一連の突出節 (16a～16e) は、中央が凸状にカーブしたパターンとされている。しかしながら、例えば円形や螺旋形といったような他のパターンも、可能である。前立腺用ステント (3) が適切に配置されたときには、一連の突出節 (16a～16e) は、患者の前立腺に対して当接する。したがって、一連の突出節 (16a～16e) は、前立腺用ステント (3) と前立腺との間の摩擦源となり、前立腺用ステント (3) の変位 (位置ズレ) を防止する。本体 (5) の一連の開口 (10, 14a～14d) は、また、患者の前立腺と前立腺用ステント (3) との間の摩擦をもたらず。一連の開口 (10, 14a～14d) は、さらに、例えば尿や血液といったような

生体流体が、前立腺用ステント（３）の本体（５）内へと流入することを可能とするとともに、前立腺組織が前立腺用ステント（３）内へと侵入することを可能とし、前立腺用ステント（３）の固定を補助して、前立腺用ステント（３）の変位を防止する。変位をさらに防止するために、先端終端部（４）は、本体（５）よりも外径を大きなものとしてベル形状とすることができる。ただし、外径は、連結セグメント（６）と実質的に同じ程度までとされる。図１２は、前立腺用ステント（３）を示す断面図である。図１２において、前立腺用ステント（３）の内部形状に関し、基端段部（１５）および先端段部（１７）に注意されたい。基端段部（１５）は、押込デバイス（１２）のフランジ（３２）（図９に図示あり）を受領し得るよう構成されている。基端段部（１５）は、押込デバイス（１２）を基端向き押し込む際には、フランジ（３２）に対する当接面をもたらず。先端段部（１７）は、ガイド（４０）（図２に図示あり）を受領し得るよう構成されている。先端段部（１７）は、前立腺用ステント（３）と連結セグメント（６）とを互いに連結した際に、ガイド（４０）に係止するための当接面をもたらず。

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【００２０】

上述したように、図１および図２に示す前立腺用ステント（３）は、少なくとも２つの個別状態を有した保持部材（８）を備えている。保持部材（８）は、第２状態となるように付勢されている。外科医は、保持部材（８）の状態を変更することができる。つまり、指でもって保持アーム（１３ａ，１３ｂ）に圧力を印加することによって縮小状態すなわち第１状態となるように、状態を変更することができる。この場合、基端チップ（２）は、基端向きに突出し、保持部材（８）が縮小する。あるいは、前立腺用ステントーカテーテルシステム（１）の管腔内において押込デバイス（１２）を基端向きに押し込むことによって、基端チップ（２）を基端向きに突出させ、保持部材（８）を縮小させることができる。後者の場合、外科医は、機構（２４）を第１位置とすることによって押込デバイス（１２）を基端向きに前進させることにより、患者の体外から縮小過程を制御することができる。この縮小過程は、図１３に概略的に示されている。同様に、保持部材（８）は、保持部材（８）に対する圧力を解除することによって、あるいは、前立腺用ステントーカテーテルシステム（１）内において押込デバイス（１２）を引き込むことによって、第２状態へと復帰させることができる。図１４は、機構（２４）を第２位置としたことの結果としての、保持部材（８）の拡張を示している。前立腺用ステント（３）から押込デバイス（１２）を取り外すには、図１５に示すように、機構（２４）を第３位置とする。

【００２１】

前立腺用ステントーカテーテルシステムの他の実施形態（１００）が、図１６に示されている。この前立腺用ステントーカテーテルシステム（１００）は、前立腺用ステント（３００）と、連結セグメント（６００）と、を備えている。前立腺用ステント（３００）は、大きなポアを有したメッシュ構成（３５０）と、基端部（３７０）と、先端部（３４０）と、基端部（３７０）から先端部（３４０）までにわたって延在する管腔と、を有している。大きなポアを有したメッシュ構成（３５０）の拡大図が、図１７に示されている。大きなポアを有したメッシュ（３５０）は、例えばナイロンやポリグリコール酸やステンレススチールやニッケルチタンベースの合金といったような、任意の自己拡張性の生体適合性材料から形成されている。大きなポアを有したメッシュ（３５０）は、選択された自己拡張性かつ生体適合性材料からなるストランドどうしの編込や織込や熱接着により、あるいは、選択された材料からなる中空チューブをスロット形成したりレーザーによってパターンカットしたり従来の機械加工したりすることにより、形成される。大きなポアを有したメッシュ（３５０）は、薄いポリマー層によってコーティングすることができ、これにより、挿入時の患者の尿路に対するトラウマを防止することができる。大きなポアを有したメッシュ内における各ポア（３６０）は、前立腺用ステント（３００）の管腔内へと流体を排出させるための開口をなしている。前立腺用ステント（３００）が、多くのポアを有していることにより、血液による閉塞のためにすべてのポア（３６０）が塞がれてしまっ排出が行えなくなるというリスクは、小さい。前立腺用ステント（３００）は、尿路の前立腺部分内に適合し得るようなサイズとされている。適切に配置されたときに

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は、基端部（３７０）は、膀胱よりも先端側に配置され、一方、先端部（３４０）は、外部括約筋よりも基端側に位置する。この実施形態においては、前立腺用ステント（３００）は、円形横断面のものとされている。横断面形状は、円形である必要はない。他の実施形態においては、大きなポアを有したメッシュを含む前立腺用ステントは、例えば三角形や楕円形といったような他の横断面形状を有することができる。さらに他の実施形態においては、前立腺用ステントの形状は、図示された実施形態とは違って、例えば砂時計形状や漏斗形状といったような非一定横断面形状のものとすることができる。

【００２２】

前立腺用ステントーカテーテルシステムの図１６に示す実施形態（１００）は、さらに、前立腺用ステント（３００）と連結セグメント（６００）とを連結するためのガイド（６４０）と、駆動機構（２４０）と流体排出用開口（２６０）とを有したハンドル（２００）と、押込デバイス（１２０）と、を備えている。押込デバイスは、弾丸形状の基端部（１２２）を有している。弾丸形状の基端部（１２２）は、前立腺用ステント（３００）の基端部（３７０）を捕獲して縮小させることができる。押込デバイスの他端には、ハンドル（２００）内に配置される駆動機構（２４０）が取り付けられている。図１８は、解放構成とされた前立腺用ステントーカテーテルシステム（１００）を示している。処置を行っている外科医は、押込デバイス（１２０）を突出させ、これにより、弾丸形状基端部（１２２）が前立腺用ステント（３００）の基端部（３７０）を解放することによって、解放構成を得ることができる。その後、外科医は、前立腺用ステント（３００）から連結セグメント（６００）を切り離すことによって、前立腺用ステントーカテーテルシステム（１００）から連結セグメント（６００）を取り外すことができ、さらに、患者の尿路から、連結セグメント（６００）とハンドル（２００）と押込デバイス（１２０）とを取り外すことができる。

【００２３】

図１６に示す前立腺用ステントーカテーテルシステム（１００）は、上述した前立腺用ステントーカテーテルシステムの先の実施形態における配置や使用や取外しの場合と同様に、患者の体内に配置され、患者の体内で使用され、患者の体から取り外される。

【００２４】

図１９～図２５に示す前立腺用ステントーカテーテルシステム（１）は、図１および図２に示す実施形態と同じものである。この実施形態においては、前立腺用ステント（３）は、上述したような保持部材（８）を備えている。図１９においては、本発明による前立腺用ステント（３）は、付勢状態すなわち自然状態とされている。図１９～図２５に示す前立腺用ステントーカテーテルシステム（１）は、さらに、少なくとも１つの縫糸（４２）を備えている。他の実施形態においては、縫糸（４２）は、例えば長尺メンブレンといったような、外部括約筋（５４）の動作を妨害することなく外部括約筋（５４）を通過し得るほど十分に薄い任意のチューブ状構造によって代替することもできる。縫糸（４２）またはチューブ状構造は、前立腺が治癒した後に所定箇所において尿路の前立腺部分から前立腺用ステント（３）を取り外す際に有効である。前立腺用ステント（３）に対して縫糸（４２）を取り付けるには、縫糸（４２）の一端を、前立腺用ステント（３）の先端終端部（４）を貫通させて縫いつける。縫糸（４２）は、血液凝固物を係止してしまつて血液凝固物を保持してしまう傾向を低減させるよう、管腔に沿って、前立腺用ステント（３）の壁および連結セグメント（６）の壁に対して平行に延在させることを意図している。縫糸（４２）の他端には、保持デバイス（４４）を設けることができる。保持デバイス（４４）は、前立腺用ステント（３）が基端側に移動した場合に、復帰手段として機能することができる。保持デバイス（４４）は、縫糸（４２）の長さ全体にわたってスライド的に位置調節することができる。このため、外科医は、保持デバイス（４４）を外側開口（６０）の内にも外にも位置させることができる。この実施形態においては、保持デバイス（４４）は、勃起を可能とし得るよう、外側開口（６０）の外側に配置されている。図１９～図２５における保持デバイス（４４）は、ビーズとされている。保持デバイスとしては、他の様々な態様が可能である。保持デバイスの他の可能ないくつかの態様は、図２６～

図 28 に示されている。

【0025】

外科医が、保持部材（8）も含めた前立腺用ステントーカテーテルシステム（1）を挿入する際には、保持部材（8）を縮小しなければならない。図 20 は、挿入状態すなわち縮小状態とされたこの実施形態における前立腺用ステントーカテーテルシステム（1）を示している。図 21～図 23 は、前立腺用ステントーカテーテルシステム（1）の挿入・配置方法を示している。図 24 および図 25 は、前立腺用ステント（3）と連結セグメント（6）との間の連結解除方法、および、その後の、患者の尿路からの連結セグメント（6）の取外し方法を示している。

【0026】

図 21 は、挿入構成（すなわち、保持部材が縮小状態とされた構成）とされた前立腺用ステントーカテーテルシステム（1）と、男性の排尿系（70）と、の双方を示している。男性の排尿系（70）は、尿路（58）と、外部括約筋（54）と、外部括約筋に対する開口（56）と、前立腺（53）と、尿路の前立腺部分（52）と、膀胱（50）と、から構成されている。前立腺用ステントーカテーテルシステム（1）の挿入箇所は、外側開口（60）である。

【0027】

膀胱排出障害を治療するためにまた（例えば、前立腺温熱療法後における）患者の生体流体の排出状況を観測するために、患者の体内に前立腺用ステントーカテーテルシステム（1）を挿入するに際しては、外科医は、前立腺用ステントーカテーテルシステム（1）を、外側開口（60）を通して患者の尿路（58）内へと挿入する。この手順は、図 22 ににおいて概略的に示されている。前立腺用ステントーカテーテルシステム（1）は、前立腺用ステント（3）が尿路の前立腺部分（52）内へと実質的に配置されかつ保持部材（8）が膀胱（50）内に配置されるまで、尿路を通して前進させられる。外科医は、連結セグメント（6）を通過して尿の流通状況を観測することによって、前立腺用ステントーカテーテルシステム（1）の適切な配置を確認することができる。図 23 は、前立腺用ステントーカテーテルシステム（1）の適切な配置状況を概略的に示している。

【0028】

前立腺用ステントーカテーテルシステム（1）は、前立腺出血の減少が観測されこれにより患者の生体流体の排出状況をもはや観測する必要がないと外科医が判断するまでは、男性の排尿系（70）内に配置される。患者の生体流体排出状況を観測する必要がなくなった場合であっても、患者の前立腺（53）は、なおも障害を受けていることがあり得る。膀胱出口障害を防止するために、また、前立腺（53）の回復を促進するために、外科医は、前立腺用ステント（3）を所定位置に残し、前立腺用ステントーカテーテルシステム（1）の連結セグメント（6）だけを取り外すことを決定することがある。連結セグメント（6）を取り外すにあたっては、外科医は、まず最初に、連結セグメント（6）を引っ張ることによって、前立腺用ステント（3）と連結セグメント（6）との連結を解除する（図 24）。次に、外科医は、尿路（58）から連結セグメント（6）を引き抜くことができる（図 25）。前立腺用ステントーカテーテルシステム（1）の連結セグメント（6）を除去した後においては、患者の外部括約筋開口（56）は、収縮することができ、外部括約筋は、通常的に動作することができる。このため、患者は、前立腺用ステント（3）を所定位置に配置している状況であるにもかかわらず、すべての膀胱機能を制御することができる。前立腺用ステント（3）に対して取り付けられた縫糸（42）は、先端終端部（4）から尿路（58）を通して延在しており、外側開口（60）の外部において終端している。縫糸（42）は、十分に薄いものであるので、外部括約筋の動作に悪影響を及ぼすことなくすなわち患者の膀胱制御性に悪影響を及ぼすことなく、収縮した外部括約筋を通過することができる。前立腺用ステント（3）の取外しは、所定期間後において、縫糸（42）を引っ張ることによりあるいは内視鏡的手段を使用することにより、個別に行うことができる。

【0029】

当業者であれば、本発明の精神および範囲を逸脱することなく、ここで開示した技術事項に対して、様々な変形や修正を行い得るであろう。本発明は、例示としての上記説明に制限されるものではない。

【図面の簡単な説明】

【図 1】本発明の一実施形態による前立腺用ステントーカテーテルシステムを概略的に示す斜視図である。

【図 2】図 1 に示す前立腺用ステントーカテーテルシステムの分解図である。

【図 3】前立腺用ステントの一実施形態を概略的に示す図である。

【図 4】前立腺用ステントの他の実施形態を概略的に示す図である。

【図 5】前立腺用ステントの他の実施形態を概略的に示す図である。

【図 6】前立腺用ステントの他の実施形態を概略的に示す図である。

【図 7】本発明による前立腺用ステントーカテーテルシステムにおける押込デバイスの一実施形態を概略的に示す図である。

【図 8】押込デバイスの他の実施形態を概略的に示す図である。

【図 9】押込デバイスの一実施形態における基端部を拡大して示す図である。

【図 10】前立腺用ステントを拡大して示す平面図である。

【図 11】図 10 に示す前立腺用ステントの側面図である。

【図 12】前立腺用ステントを、図 10 における 8-8 線に沿った断面でもって示す断面図である。

【図 13】第 1 位置とされたハンドル機構と、対応した縮小状態とされた前立腺用ステントと、この前立腺用ステントと係合した押込デバイスと、を概略的に示す図である。

【図 14】第 2 位置とされたハンドル機構と、対応した拡張状態とされた前立腺用ステントと、この前立腺用ステントと係合した押込デバイスと、を概略的に示す図である。

【図 15】第 3 位置とされたハンドル機構と、対応した拡張状態とされた前立腺用ステントと、この前立腺用ステントから係合解除された押込デバイスと、を概略的に示す図である。

【図 16】前立腺用ステントーカテーテルシステムの他の実施形態を、挿入状態でもって示す平面図である。

【図 17】図 16 における前立腺用ステントを拡大して示す平面図である。

【図 18】図 16 における前立腺用ステントを、解放状態でもって示す図である。

【図 19】図 1 に示す前立腺用ステントーカテーテルシステムを、拡張状態でもって示す図である。

【図 20】図 19 に示す前立腺用ステントーカテーテルシステムを、挿入状態でもって示す図である。

【図 21】男性の排尿系と、挿入前における図 20 の前立腺用ステントーカテーテルシステムと、を概略的に示す図である。

【図 22】図 20 の前立腺用ステントーカテーテルシステムを挿入する様子を概略的に示す図である。

【図 23】図 19 の前立腺用ステントーカテーテルシステムの適正な配置状況を概略的に示す図である。

【図 24】図 19 の前立腺用ステントーカテーテルシステムからの連結セグメントの連結解除を概略的に示す図である。

【図 25】男性の排尿系からの連結セグメントの取外しを概略的に示す図である。

【図 26】保持デバイスの一実施形態を拡大して概略的に示す図である。

【図 27】保持デバイスの他の実施形態を拡大して概略的に示す図である。

【図 28】保持デバイスの他の実施形態を拡大して概略的に示す図である。

【符号の説明】

- 1 前立腺用ステントーカテーテルシステム
- 3 前立腺用ステント
- 4 先端終端部

10

20

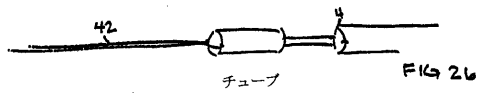
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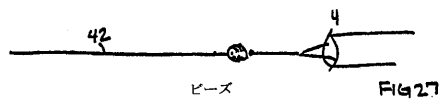
50

5	本体	
6	連結セグメント	
7	基端部	
8	保持部材	
1 2	押込デバイス	
1 3 a	保持アーム (アーム)	
1 3 b	保持アーム (アーム)	
1 6 a	突出節 (突出部分)	
1 6 b	突出節 (突出部分)	
1 6 c	突出節 (突出部分)	10
1 6 d	突出節 (突出部分)	
1 6 e	突出節 (突出部分)	
2 0	ハンドル	
2 2	開口	
2 4	機構	
2 6	側部開口	
2 8	基端部	
2 9	長尺本体	
3 0	先端部	
3 4	先端部 (外部端)	20
3 6	基端部 (挿入端)	
4 2	縫糸	
5 0	膀胱	
5 2	尿路の前立腺部分	
5 4	外部括約筋	
5 8	尿路	
6 0	外側開口	
1 0 0	前立腺用ステントーカテーテルシステム	
1 2 0	押込デバイス	
2 0 0	ハンドル	30
2 4 0	駆動機構 (機構)	
2 6 0	流体排出用開口 (開口)	
3 0 0	前立腺用ステント	
3 4 0	先端部	
3 5 0	大きなポアを有したメッシュ構成	
3 7 0	基端部	
6 0 0	連結セグメント	

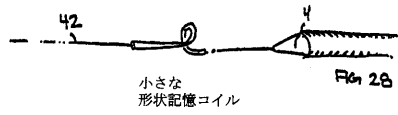
【図 26】



【図 27】



【図 28】



【国際公開パンフレット】

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
9 August 2001 (09.08.2001)

PCT

(10) International Publication Number
WO 01/56629 A2

- (51) International Patent Classification: A61M 1/00 (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (21) International Application Number: PCT/US01/03001
- (22) International Filing Date: 30 January 2001 (30.01.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/180,131 3 February 2000 (03.02.2000) US
60/188,002 9 March 2000 (09.03.2000) US
09/733,752 8 December 2000 (08.12.2000) US
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- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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(54) Title: FACILITATING DRAINAGE

(57) Abstract: A prostatic stent comprises a body member and a retaining member. The body member includes a distal terminating end, a proximal end portion, and a lumen extending within the body member to allow fluid drainage through the body member. The body member is sized for placement substantially within the prostatic section of the urethra, with the distal terminating end located proximal of an external sphincter to allow normal operation of the external sphincter. The retaining member extends from the proximal end portion of the body member. The retaining member is collapsible into a first state to allow passage of the prostatic stent into the urethra, and the retaining member is expandable into a second state when located in a bladder to hold the body member in place substantially within the prostatic section of the urethra.

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FACILITATING DRAINAGE

Cross-Reference to Related Applications

This claims priority to and the benefit of each of the following two provisional U.S. patent applications: serial number 60/180,131 filed on February 3, 2000, and serial number 60/188,002 filed on March 9, 2000.

Technical Field

- 5 This invention relates to facilitating drainage and, more particularly, to facilitating fluid drainage from the bladder and through the urethra of a patient.

Background Information

- 10 The prostate is a gland in the male urinary system located directly below the bladder and around the urethra. In some men, especially men over fifty years of age, the prostate can become swollen or enlarged due to disease or infection. The enlarged prostate constricts the urethra causing discomfort and/or bladder outlet obstruction.

- One of the known procedures for treating an enlarged prostate is thermal prostatic therapy. During thermal prostatic therapy, the prostate is heated above body temperature to remove the diseased tissue, whereby returning the prostate to normal size. Immediately after
15 treatment, however, the prostate is still swollen or enlarged due to the therapeutic trauma induced by the procedure. It may take several weeks before the treated prostate recovers and no longer inhibits bladder drainage.

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Summary of the Invention

The invention involves providing drainage of fluid from the bladder of a patient. Systems and methods of the invention typically are used after the patient has undergone prostate treatment such as thermal therapy. Systems and methods according to the invention involve converting in situ a urinary drainage catheter into an indwelling device. The device maintains the prostatic section of the urethra open and able to pass fluid while also allowing normal operation of the patient's external sphincter such that the patient has full and normal control over the retention and discharge of urine from the bladder even with the device in place within the prostatic section of the urethra.

In general, in one aspect, the invention relates to a prostatic stent. The prostatic stent comprises a body member and a retaining member. The body member includes a distal terminating end, a proximal end portion, and a lumen extending within the body member to allow fluid to drain through the body member. The directional terms proximal and distal require a point of reference. In this application, the point of reference in determining direction is in the perspective of the patient. Therefore, the term proximal will always refer to a direction that points into the patient's body, whereas distal will always refer to a direction that points out of the patient's body. The body member is sized for placement substantially within the prostatic section of the urethra. The distal terminating end is positioned proximal of an external sphincter so as to allow normal operation of the external sphincter. The retaining member extends from the proximal end portion of the body member. The retaining member is collapsible into a first state to allow the passage of the prostatic stent into the urethra in the first instance. The retaining member also is expandable into a second state when located in the bladder to hold the body member in place substantially within the prostatic section of the urethra.

Embodiments of this aspect of the invention can include the following features. The retaining member of the prostatic stent can be tapered to provide comfort to the patient during insertion of the stent into the patient's urethra. The retaining member also can comprise two or more retaining arms, and the retaining arms can be biased in the second state. Prior to and during insertion of the prostatic stent into the patient's urethra, the retaining member is in the first state. The retaining member returns to substantially the second state once in the patient's bladder and thereby acts as an anchor to keep the body member of the prostatic stent substantially within the prostatic section of the urethra. The body member of the prostatic stent can include one or more side openings to allow fluid to drain from the prostatic section of the urethra into the lumen. To

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help prevent migration of the prostatic stent, the body member also can have one or more protrusions. The protrusions are designed to engage the wall of the prostatic urethra and thereby provide a source of friction that limits the motion of the prostatic stent within the urethra. The body member also can include a suture attached to the distal terminating end. The suture should
5 be long enough to extend from the body member to the patient's meatus. The prostatic stent can be removed easily from the patient's body by pulling on the suture. The end of the suture can be connected to a ball, ring, coil, or other structure that either extends out of the body entirely or is located within the meatus. The point of the ball, ring, coil or other structure at the end of the suture is to facilitate location of the end of the suture and then removal of the stent by the patient
10 himself or by a medical professional, simply by pulling on the located suture.

In another aspect, the invention relates to a prostatic stent-catheter system for draining fluid from the bladder, through the prostatic urethra, and out of the patient's body. The prostatic stent-catheter comprises a stent and a connecting segment. The stent includes a body member comprising a distal terminating end, a proximal end portion, and a lumen extending within the
15 body member. The body member is sized for placement substantially within the prostatic section of the urethra with the distal terminating end located proximal of the external sphincter to allow normal operation of the external sphincter. The connecting segment comprises an elongated body member including a distal end, a proximal end, and a lumen. The proximal end of the connecting segment is releasably coupled to the distal terminating end of the stent. The prostatic
20 stent-catheter system has at least two modes of operation after being inserted into the patient's urethra. In a first mode, the stent and connecting segment are coupled together, and drainage of fluid from the bladder occurs continuously. In a second mode, the connecting segment is decoupled from the stent in situ, and the connecting segment then is removed from the patient's urethra. After the connecting segment is removed from the patient's body, the patient's external
25 sphincter contracts and is allowed to function normally to allow the patient have full control over voiding of urine.

Embodiments of this aspect of the invention can include the following features. The stent portion of the prostatic stent-catheter can further include a retaining member extending proximally away from the body member. When the stent-catheter system is properly positioned,
30 the retaining member will be located in the patient's bladder. In one embodiment the retaining member comprises a proximal curved tip that acts as an anchor within the bladder opening to prevent the distal migration of the stent. In another embodiment, the retaining member includes

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at least two retaining arms biased in an expanded state. The retaining arms are collapsible and are collapsed prior and during the insertion of the prostatic stent-catheter into the patient's urethra. The retaining arms in the present embodiment return to the expanded state once located in the patient's bladder and thereby act as an anchor to prevent stent migration. The contraction and the expansion of the retaining arms can be controlled through a pushing device while the prostatic stent-catheter is within the patient's body. The stent portion of the prostatic stent-catheter system can further include a body member comprising of a large pore mesh. The large pore mesh can be fabricated from any biocompatible, self-expanding material such as a nickel-titanium based alloy. The body member including the large pore mesh frictionally engages the patient's prostate, whereby anchoring the stent to prevent migration.

In general, in still another aspect, the invention relates to a method of placing a prostatic stent-catheter system within the urethra. The prostatic stent-catheter system, which includes a stent and a connecting segment releasably coupled to one another, is inserted into the urethra of the patient. A medical professional such as a physician advances the prostatic stent-catheter system through the urethra until at least a portion of the stent is positioned substantially within the prostatic section of the urethra. When properly positioned, at least a portion of the stent will reside within the prostatic section of the urethra, while the connecting segment will extend through the external sphincter, through the rest of the urethra, and outside of the patient's body. The physician will know that the prostatic stent-catheter system is properly positioned when urine or other bodily fluid is observed draining through the distal end of the connecting segment. Bodily fluids such as urine and blood draining through the prostatic stent-catheter system are monitored. If the procedure is being done after treatment (e.g., surgery) on the prostate, the medical professional must determine when the patient's prostate has recovered or is recovering sufficiently from the treatment, and then the professional decouples the connecting segment from the stent and withdraws the connecting segment entirely from the patient's body. The stent thus remains within the prostatic section of the urethra to prevent bladder outlet obstruction and to keep the prostatic section of the urethra open and passing fluid(s) from the bladder while allowing normal operation of the patient's external sphincter. Once the prostate has fully recovered and poses no risk of obstructing fluid drainage, the stent can be removed. Removal of the indwelling stent can be accomplished by pulling on a suture attached to the stent. The suture typically is left extending from the urethra outside of the patient's body, or it can be left just

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within the meatus and therefore easily located by the patient himself or a medical professional such as a doctor or nurse.

The foregoing and other objects, aspects, features, and advantages of the invention will become more apparent from the following description and from the claims.

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Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

- 5 FIG. 1 is a schematic view of a prostatic stent-catheter system according to one embodiment of the present invention.
- FIG. 2 is an exploded view of the prostatic stent-catheter system shown in FIG. 1.
- FIG. 3 is a schematic view of one embodiment of a prostatic stent.
- FIG. 4 is a schematic view of another embodiment of a prostatic stent.
- 10 FIG. 5 is a schematic view of another embodiment of a prostatic stent.
- FIG. 6 is a schematic view of another embodiment of a prostatic stent.
- FIG. 7 is a schematic view of one embodiment of a pushing device of a prostatic stent-catheter system according to the invention.
- FIG. 8 is a schematic view of another embodiment of a pushing device.
- 15 FIG. 9 is an enlarged view of the proximal end of one embodiment of a pushing device.
- FIG. 10 is an enlarged plan view of a prostatic stent.
- FIG. 11 is a side view of the prostatic stent shown in FIG. 10.
- FIG. 12 is a cross-sectional view of the prostatic stent taken along the lines 8-8 in FIG. 10.
- 20 FIG. 13 is a schematic view of both a handle mechanism in a first position and a corresponding collapsed prostatic stent configuration with an engaged pushing device.
- FIG. 14 is a schematic view of both a handle mechanism in a second position and a corresponding expanded prostatic stent configuration with an engaged pushing device.
- FIG. 15 is a schematic view of both a handle mechanism in a third position and a corresponding expanded prostatic stent configuration with a disengaged pushing device.
- 25 FIG. 16 is a plan view of another embodiment of a prostatic stent-catheter system, in an insertion configuration.
- FIG. 17 is an enlarged plan view of the prostatic stent shown in FIG. 16.
- FIG. 18 is the prostatic stent-catheter system of FIG. 16 in a release configuration.
- 30 FIG. 19 is a schematic view of the prostatic stent-catheter system of FIG. 1, showing the prostatic stent-catheter system in an expanded configuration.

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FIG. 20 is a schematic view of the prostatic stent-catheter system of FIG. 19 in an insertion configuration.

FIG. 21 is a schematic view of a male urinary system and the prostatic stent-catheter system of FIG. 20 prior to insertion.

5 FIG. 22 is a schematic view illustrating insertion of the prostatic stent-catheter system of FIG. 20.

FIG. 23 is a schematic view illustrating proper placement of the prostatic stent-catheter system of FIG. 19.

10 FIG. 24 is a schematic view illustrating connecting segment decoupling from the prostatic stent-catheter system of FIG. 19.

FIG. 25 is a schematic view illustrating connecting segment removal from the male urinary system.

FIG. 26 is an enlarged schematic view of one embodiment of a retaining device.

FIG. 27 is an enlarged schematic view of another embodiment of a retaining device.

15 FIG. 28 is an enlarged schematic view of another embodiment of a retaining device.

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Description

The invention generally relates to relieving bladder outlet obstruction. After prostate treatment, a patient can experience urinary retention. The invention generally involves treating urinary retention, especially male urinary retention, while still allowing normal operation of the patient's external sphincter (and thus allowing normal voiding of the bladder) even with a stent located temporarily within the prostatic section of the patient's urethra.

After a medical procedure to treat an obstructed prostate, such as thermal prostate therapy, a patient may experience prostate bleeding while the recently-treated prostate recovers. Another consequence of such medical procedures is bladder outlet obstruction which results from the still-slightly enlarged and recovering prostate. After the procedure, the medical professional (e.g., a physician) that performed the procedure or some other medical professional will monitor the amount of urine and prostate bleeding, and attempt to provide the patient with an open urinary passageway. In order to monitor continuously the bodily fluids from the patient's bladder and prostate, the medical professional(s) attending to the patient need to prevent the patient's external sphincter from closing to allow constant and uninterrupted drainage of those bodily fluids. In general, the attending professional(s) only need(s) to monitor the flow of blood and urine from the patient's urinary system for a few hours. It may, however, take several weeks for the patient's prostate to recover. One of the objects of the present invention is to provide devices, systems, and methods which will maintain an open passageway throughout the patient's entire urinary system such that constant drainage can be realized for some period of time just after treatment of the prostate, and which also can thereafter provide an open urinary passageway from the bladder through the prostatic section of the urethra while simultaneously allowing normal operation of the patient's external sphincter such that the patient has full and normal control over bladder voiding.

Referring to FIGS. 1 and 2, a prostatic stent-catheter system 1 of the invention comprises a prostatic stent 3 and a connecting segment 6. The prostatic stent 3 includes a body member 5 made of one or more biocompatible materials such as silicone, nylon, polyglycolic acid, or stainless steel, and sized to fit substantially within the prostatic section of the urethra. The body member 5 has a proximal end 7, a distal terminating end 4, and a lumen extending from the proximal end 7 to the distal terminating end 4 to allow fluid drainage through the body member 5. As previously mentioned in this application, the term proximal refers to a direction that points into the patient's body and the term distal refers to a direction that points out of the patient's

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body. The body member 5 may be reinforced with a wire mesh to increase the tensile strength of the prostatic stent 3 whereby decreasing the possibility of the lumen collapsing. The prostatic stent 3 as illustrated in FIGS. 1 and 2 further comprises a retaining member 8. The retaining member 8 is also made from one or more biocompatible materials. In the disclosed embodiment, the retaining member 8 has at least two retaining arms 13a and 13b. Other retaining member 8 embodiments are possible, so long as these embodiments anchor the body member 5 within the prostatic section of the urethra, and do not inhibit fluid drainage from the bladder. Examples of some other retaining members are given in FIGS. 3-6. Other further possible embodiments of retaining member shapes include umbrella shaped prongs and a pigtail curl. All retaining member embodiments must be either collapsible or able to be straighten for insertion ease. Similarly, a retaining member is not required if a prostatic stent includes another means to prevent migration of the prostatic stent from the prostatic section of the urethra (for example, a body member that frictionally engages the patient's prostate). The retaining member 8, as shown as in the embodiment of the device in FIGS. 1-2, also includes a proximal tip 2. Within the proximal tip 2, there is a lumen extending from a base proximal tip opening 9 to a proximal tip opening 11. The retaining member 8 is collapsible and has at least two distinct states. In a first state, the retaining member 8 is collapsed to allow for insertion ease. In a second state, the retaining member 8 is expanded to secure the prostatic stent 3 from significant migration after the prostatic stent 3 has been properly positioned. The prostatic stent 3 is properly positioned within a male patient's urinary system, when the retaining member 8 is located within the patient's bladder and the body member 5 is located substantially within the prostatic section of the urethra with the distal terminating end 4 being located proximal to the patient's external sphincter. The connecting segment 6 of the prostatic stent-catheter system 1 comprises an elongated body member 29 having a proximal end 28 and a distal end 30. A lumen extends from the proximal end 28 to the distal end 30 for fluid drainage. At the distal end 30 of the connecting segment 6 there is at least one side opening 26 for fluid drainage.

During insertion of the prostatic stent-catheter system 1, the proximal end 28 of the connecting segment 6 is releasably coupled to the distal terminating end 4 of the prostatic stent 3. The coupling of the prostatic stent 3 with the connecting segment 6 creates a single lumen extending from the proximal end 7 of the body member 5 to the distal end 30 of the connecting segment 6. To couple the prostatic stent 3 to the connecting segment 6 a guide 40 is used. The guide 40 is an open ended tubular body member having a slightly smaller diameter than both the

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connecting segment 6 and the body member 5. The guide 40 is fastened to the proximal end 28 of the connecting segment 6 such that a portion of the guide 40 is within the lumen of the connecting segment 6 and the remaining portion extends out from the proximal end 28 of the connecting segment 6. The remaining portion of the guide 40 is then inserted into the lumen of the body member 5 creating a slip-fit seal between the prostatic stent 3 and the connecting segment 6. Various other couplings are possible, so long as the distal terminating end 4 of the body member 5 and the proximal end 28 of the connecting segment 6 are releasably joined together. For example, in other embodiments, the guide 40 is releasably coupled to the prostatic stent 3 with sutures that can be removed in situ after the prostatic stent 3 is properly positioned.

After a prostatic procedure to treat an obstructed prostate, such as thermal therapy, the patient's prostate typically will still be slightly enlarged and it may bleed. To prevent bladder obstruction and to monitor the amount of urine production and prostate bleeding, a physician can insert the prostatic stent-catheter 1 into a patient's urethra until the proximal tip 2 is located within the bladder and the connecting segment 6 extends through the external sphincter as to allow constant drainage of fluids from the patient's bladder and through the patient's prostate. Once the physician has decided that the patient's bodily fluids no longer need to be monitored, constant fluid drainage from the patient's bladder is no longer necessary. To avoid the potential risk of bladder retention due to the slightly enlarged and recently treated prostate, however, the physician may wish to maintain the prostatic stent 3 within the prostatic section of the urethra until the prostate is completely resolved. The physician, realizing that patient's prostate could take several weeks to resolve and not wishing to inconvenience the patient, can remove the connecting segment 6 from the prostatic stent-catheter system 1 while leaving the prostatic stent 3 in place by simply pulling on the connecting segment 6.

The embodiment of the prostatic stent-catheter system 1 of FIGS. 1 and 2 further comprises a pushing device 12 and a handle 20. The pushing device 12 has a proximal end 36 and a distal end 34. The width of the pushing device 12 is sized to fit within the lumens of the prostatic stent 3 and the connecting segment 6; while the length of the pushing device 12 is sized so that the proximal end 36 can contact the proximal tip 2 of the prostatic stent 3 while the distal end 34 extends beyond the distal end 30 of the releasably connected connecting segment 6.

Therefore, the physician performing the procedure can use the pushing device 12 to contact the proximal tip 2 of the prostatic stent 3 once the prostatic stent-catheter system 1 is already inserted into the patient's body. The pushing device 12 can be made from any material that is flexible

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enough to conform to the patient's anatomy, but also rigid enough to extend the proximal tip 2 away from the body member 5. Materials such as stainless steel or polycarbonate meet these criteria. The pushing device 12 can be either straight as shown in FIG. 7 or curved as shown in FIG. 8, to aid in the insertion and placement of the prostatic stent 3 within the prostatic section of the urethra. Extending through the entire pushing device 12 is a lumen capable of receiving a guide wire. At the proximal end 36 of the pushing device 12 is a flange 32 used to connect the proximal tip 2 to the pushing device 12. The flange 32 also prevents premature separation of the pushing device 12 from the proximal tip 2. The flange 32 is best illustrated in FIG. 9. The other end of the pushing device, the distal end 34, is attached to a mechanism 24 located within the handle 20. The mechanism 24 is slidably movable in the proximal and distal directions. Because the mechanism 24 is attached to the pushing device 12, the position of the mechanism 24 determines the position of the pushing device 12 within the prostatic stent-catheter system 1. The handle 20 is attached to the distal end 30 of the connecting segment and remains outside of the patient's body. Therefore, a physician has access to the position of the pushing device 12 at all times during a procedure. Besides the mechanism 24, the handle 20 also includes at least one opening 22 for drainage of fluids from the prostatic stent-catheter system 1.

The embodiment of the prostatic stent 3 of FIGS. 1 and 2 includes a series of openings 10, 14a - 14d in communication with the lumen of the body member 5, and a series of protuberances 16a - 16e. These features are most clearly illustrated in FIGS. 10-12. The series of openings 10, 14a-14d and/or the series of protuberances 16a-16e on the body member 5 decrease the likelihood of migration of the prostatic stent 3. The protuberances may be parallel to each other or may be progressively angled to further decrease migration. In the disclosed embodiment, the series of protuberances 16a - 16e have a serpentine pattern, however other possible patterns such as circular or spiral are possible. When the prostatic stent 3 is properly positioned, the series of protuberances 16a-16e are in contact with the patient's prostate. Consequently, the series of protuberances 16a - 16e create a source of friction between the prostatic stent 3 and the prostate which decreases movement of the prostatic stent 3. The series of openings 10, 14a-14d in the body member 5 also create friction between the patient's prostate and the prostatic stent 3. The series of openings 10, 14a- 14d further allow bodily fluids such as urine or blood to enter into the body member 5 of the prostatic stent 3 while permitting prostate tissue to extend into the prostatic stent 3 to aid in securing the prostatic stent 3 from migrating. To further prevent migration, the distal terminating end 4 may be belled outward to a diameter

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larger than the body member 5 but essentially equal to the connecting segment 6. FIG. 12 is a cross sectional view of the prostatic stent 3. In this drawing a proximal ledge 15 and a distal ledge 17 are noticeable in the internal prostatic stent 3 profile. The proximal ledge 15 is designed to receive the flange 32 of the pushing device 12 (shown in FIG. 9). The proximal ledge 15 provides a contact surface for the flange 32 to push against when the pushing device 12 is proximally extended. The distal ledge 17 is designed to receive the guide 40 (shown in FIG. 2). The distal ledge 17 provides a contact surface for the guide 40 to rest against while the prostatic stent 3 and the connecting segment 6 are coupled together.

As previously discussed, the prostatic stent 3 as illustrated in FIGS. 1 and 2 includes a retaining member 8 with at least two distinct states. The retaining member 8 is biased in the second state. The physician can change the retaining member's 8 configuration to the collapsed or first state by either applying pressure with his or her fingers to the retaining arms 13a - 13b to extend the proximal tip 2 in the proximal direction and thus collapse the retaining member 8 or by proximally extending the pushing device 12 within the lumen of the prostatic stent-catheter system 1 to extend the proximal tip 2 and thereby collapse the retaining member 8. In the latter case, the physician can control the process from outside of a patient's body by placing the mechanism 24 into a first position causing the extension of the pushing device 12. This process is schematically illustrated in FIG. 13. Similarly, the retaining member 8 can be returned to the second state by either removing the pressure on the retaining member 8 or retracting the pushing device 12 within the prostatic stent-catheter system 1. FIG. 14 shows the expansion of the retaining member 8 as a result of placing the mechanism 24 in a second position. To detach the pushing device 12 from the prostatic stent 3, the mechanism 24 is placed into a third position, shown in FIG. 15.

Another embodiment of a prostatic stent-catheter system 100 is illustrated in FIG. 16.

The prostatic stent-catheter system 100 comprises a prostatic stent 300 and a connecting segment 600. The prostatic stent 300 includes a large pore mesh design 350, a proximal end 370, a distal end 340, and a lumen extending between the proximal end 370 and the distal end 340. An enlarged view of the large pore mesh design 350 is illustrated in FIG. 17. The large pore mesh 350 is fabricated from any self-expanding, biocompatible material such as nylon, polyglycolic acid, stainless steel or nickel-titanium based alloys. The large pore mesh 350 is produced by weaving, braiding, or heat bonding strands of the selected self-expanding, biocompatible materials together or by slotting or pattern cutting by laser and/or conventional machining a

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hollow tube of the selected material. The large pore mesh 350 may be coated with a thin polymeric layer to prevent trauma to the patient's urethra during insertion. Each pore 360 in the large pore mesh is an opening for fluids to drain into the lumen of the prostatic stent 300.

Because the prostatic stent 300 includes many pores, the possibility of all of the pores 360

- 5 becoming blocked by blood clots so as to inhibit drainage is small. The prostatic stent 300 is sized to fit within the prostatic section of the urethra. When properly positioned the proximal end 370 is located distal to the bladder while the distal end 340 terminates proximal to the external sphincter. In the disclosed embodiment, the prostatic stent 300 has a circular cross section. The shape of the cross section need not be circular. In other embodiments, a prostatic
- 10 stent including a large pore mesh can have other cross sectional shapes such as a triangle or oval. In still yet other embodiments, the shape of a prostatic stent could differ from the disclosed embodiment by having a non-constant cross sectional shape such as hourglass or funnel shapes.

- The prostatic stent-catheter system 100 of the embodiment illustrated in FIG. 16 further includes a guide 640 for coupling the prostatic stent 300 to the connecting segment 600, a handle
- 15 200 including an activation mechanism 240 and openings for fluid drainage 260, and a pushing device 120. The pushing device has a bullet-shaped proximal end 122. The bullet-shaped proximal end 122 is capable of capturing and collapsing the proximal end 370 of the prostatic stent 300. The opposite end of the pushing device is attached to the activation mechanism 240 in the handle 200. FIG. 18 illustrates the prostatic stent-catheter system 100 in a release
- 20 configuration. The physician performing the procedure can achieve the release configuration by extending the pushing device 120 so that the bullet-shaped proximal end 122 releases the proximal end 370 of the prostatic stent 300. The physician can then remove the connecting segment 600 from the prostatic stent-catheter system 100 by decoupling the connecting segment 600 from the prostatic stent 300, and removing the connecting segment 600, the handle 200, and
- 25 pushing device 120 from the patient's urethra.

The prostatic stent-catheter system 100 illustrated in FIG. 16 is placed into the patient's body, used in the patient's body, and removed from the patient's body in the same way that the other embodiments of prostatic stent-catheter systems described herein are placed, used, and removed.

- 30 The prostatic stent-catheter system 1 in FIGS. 19-25 is of the embodiment illustrated in FIGS. 1 and 2. In this embodiment, the prostatic stent 3 further comprises a retaining member 8 as previously described. In FIG. 19, the prostatic stent 3 in this invention is in its biased or

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natural state. The prostatic stent-catheter system 1 in FIGS. 19-25 further includes at least one suture 42. In another embodiment, the suture 42 can be replaced with any tubular structure that is thin enough to pass through the external sphincter 54 without negatively impacting the operation of the external sphincter 54 such as a long membrane. The suture 42 or tubular structure can be useful when removing the prostatic stent 3 from the prostatic section of the urethra at some point after the prostate has resolved. To attach the suture 42 to the prostatic stent 3 one end of the suture 42 is threaded through the distal terminating end 4 of the prostatic stent 3. The suture 42 is intended to run parallel to the prostatic stent 3 and connecting segment 6 walls along the lumen to reduce the likelihood of catching and holding blood clots. The other end of the suture 42 can be attached or connected to a retaining device 44. The retaining device 44 serves as a recovery means if the prostatic stent 3 proximally migrates. The retaining device 44 is slidably adjustable along the entire length of the suture 42, thereby allowing the physician to be able to position the retaining device 44 either within or external to the meatus 60. In the disclosed embodiment, the retaining device 44 is located external to the meatus 60 to permit erections. The retaining device 44 in FIGS. 19-25 is a bead. Various other embodiments of retaining devices are possible. Some of the other possible embodiments of retaining devices are illustrated in FIGS. 26-28.

Before a physician can insert the prostatic stent-catheter system 1 including a retaining member 8, the retaining member 8 must be collapsed. FIG. 20 shows a prostatic stent-catheter system 1 of a disclosed embodiment in an insertion or collapsed configuration. FIGS. 21-23 illustrate a method of inserting and placing a prostatic stent-catheter system 1. The remaining drawings, FIGS. 24-25 depict the decoupling of the prostatic stent 3 and the connecting segment 6 and the subsequent removal of the connecting segment 6 from a patient's urethra.

FIG. 21 shows an illustration of both the prostatic stent-catheter system 1 in the insertion configuration (i.e., collapsed retaining member), and a male urinary system 70. The male urinary system 70 including a urethra 58, an external sphincter 54, an opening to the external sphincter 56, a prostate 53, a prostatic section of the urethra 52, and a bladder 50. The point of insertion of the prostatic stent-catheter system 1 is the meatus 60.

To position the prostatic stent-catheter system 1 within a patient to relieve bladder outlet obstruction and to monitor a patient's bodily fluid excretions (post thermal prostate therapy, for example), a physician inserts the prostatic stent-catheter system 1 into a patient's urethra 58 through the meatus 60. This procedure is schematically illustrated in FIG 22. The prostatic

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stent-catheter system 1 is advanced through the urethra until the prostatic stent 3 is substantially within the prostatic section of the urethra 52 with the retaining member 8 residing in the bladder 50. The physician can confirm proper placement of the prostatic stent-catheter system 1 by observing urine flowing through the connecting segment 6. FIG. 23 illustrates schematically the proper placement of a prostatic stent-catheter system 1.

The prostatic stent-catheter system 1 remains inside the male urinary system 70 until a decrease in prostate bleeding is observed and a physician decides that it is no longer necessary to monitor a patient's bodily fluid excretions. Even though a patient's bodily fluid excretions no longer require monitoring, the patient's prostate 53 may still be obstructed. To prevent bladder outlet obstruction and to promote prostate 53 recovery, a physician may decide to leave the prostatic stent 3 in position, and to remove only the connecting segment 6 portion of the prostatic stent-catheter system 1. To remove the connecting segment 6, the physician first decouples the prostatic stent 3 and connecting segment 6 by pulling on the connecting segment 6 (FIG. 24). The physician is then able to withdraw the connecting segment 6 from the urethra 58 (FIG. 25). Once the connecting segment 6 portion of the prostatic stent-catheter system 1 is removed, the patient's external sphincter opening 56 contracts, allowing the external sphincter to operate normally and thus allowing the patient to control all bladder functions even though the prostatic stent 3 remains in place. The suture 42 attached to the prostatic stent 3 extends from the distal terminating end 4 through the urethra 58 and terminates just outside the meatus 60. The suture 42 is thin enough to pass through the contracted external sphincter opening 56 without negatively impacting the operation of the external sphincter or therefore the patient's bladder control. The removal of a prostatic stent 3 may be performed separately at some later time, by either pulling on the suture 42 or through endoscopic means.

Variations, modifications, and other implementations of what is described herein will occur to those of ordinary skill in the art without departing from the spirit and the scope of the invention. The invention is not to be limited by the preceding illustrative description.

What is claimed is:

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Claims

- 1 1. A prostatic stent, comprising:
 - 2 (a) a body member including a distal terminating end, a proximal end portion, and a
 - 3 lumen extending within the body member, the body member sized for placement
 - 4 substantially within the prostatic section of the urethra with the distal terminating
 - 5 end located proximal of an external sphincter; and
 - 6 (b) a retaining member extending from the proximal end portion of the body member,
 - 7 the retaining member being collapsible and expandable.
 - 1 2. The device of claim 1 wherein a proximal portion of the retaining member is
 - 2 tapered.
 - 1 3. The device of claim 1 wherein the retaining member is formed integrally with the
 - 2 body member.
 - 1 4. The device of claim 1 wherein the retaining member is biased in an expanded
 - 2 state.
 - 1 5. The device of claim 1 wherein the retaining member comprises at least two arms
 - 2 biased in the expanded state.
 - 1 6. The device of claim 1 wherein the body member comprises at least one side
 - 2 opening in communication with the lumen.
 - 1 7. The device of claim 1 wherein the body member includes at least one protrusion
 - 2 to aid retention of the body member substantially within the prostatic section of
 - 3 the urethra.
 - 1 8. The device of claim 1 wherein the body member comprises a flexible, compliant
 - 2 material capable of maintaining the lumen when located within the urethra.
 - 1 9. The device of claim 1 further comprising a suture extending from the medical
 - 2 device through the urethra, and terminating externally of the meatus to allow
 - 3 removal of the medical device from the urethra by pulling the suture.
 - 1 10. A prostatic stent-catheter system for draining fluid from the bladder and through
 - 2 the prostate after prostate treatment, comprising:

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- 3 (a) a stent comprising a body member including a distal terminating end, a proximal
 4 end portion, and a lumen extending within the body member, the body member
 5 sized for placement substantially within the prostatic section of the urethra with
 6 the distal terminating end located proximal of the external sphincter; and
 7 (b) a connecting segment comprising an elongated body member including a distal
 8 end located outside of a patient's body, a proximal end releasably coupled to the
 9 distal terminating end of the stent, and a lumen extending within the elongated
 10 body member.
- 1 11. The prostatic stent-catheter system according to claim 10 wherein the stent further
 2 comprises a retaining member extending from the proximal end portion of the
 3 body member, the retaining member capable of holding the body member
 4 substantially within the prostatic section of the urethra.
- 1 12. The prostatic stent-catheter system according to claim 10 wherein the stent further
 2 comprises a retaining member extending from the proximal end portion of the
 3 body member, the retaining member being collapsible and expandable.
- 1 13. The prostatic stent-catheter system according to claim 12 further comprising:
 2 (a) a pushing device slidably receivable by the prostatic stent-catheter system, the
 3 pushing device including an insertion end and an external end, the pushing device
 4 sized to allow the insertion end to contact the proximal end portion of the stent
 5 while the external end remains outside the patient's body; and
 6 (b) a handle secured to the distal end of the connecting segment, the handle including
 7 at least one opening to allow fluid drainage out of the handle, and a mechanism,
 8 the mechanism being attached to the pushing device to allow a physician to
 9 control the position of the pushing device within the lumen of the connecting
 10 segment and the lumen of the stent.
- 1 14. The handle according to claim 13 wherein moving the mechanism:
 2 (a) to a first position proximally extends the pushing device resulting in the collapse
 3 of the retaining member of said stent,
 4 (b) to a second position proximally retracts the pushing device resulting in the
 5 expansion of the retaining member of said stent, and

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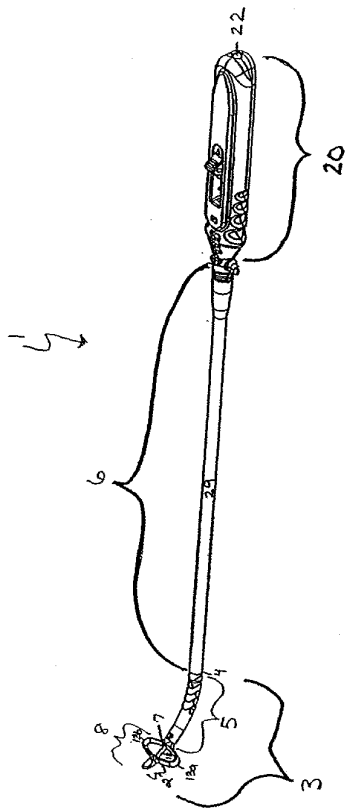
- 6 (c) to a third position proximally retracts the pushing device resulting in the absence
7 of contact between the pushing device and the proximal end portion of said stent.
- 1 15. The pushing device according to claim 13 wherein the insertion end is straight.
- 1 16. The pushing device according to claim 13 wherein the insertion end is curved.
- 1 17. The prostatic stent-catheter system according to claim 10 wherein the stent further
2 includes a self-expanding, biocompatible material and a large pore mesh design.
- 1 18. The prostatic stent-catheter system according to claim 17 further comprising:
2 (a) a pushing device slidably receivable by the prostatic stent-catheter system, the
3 pushing device including an insertion end and an external end, the insertion end
4 being able to restrain the proximal end portion of the stent, the pushing device
5 sized to allow the insertion end to restrain the proximal end portion of the stent
6 while the external end remains outside the patient's body; and
7 (b) a handle secured to the distal end of the connecting segment, the handle including
8 at least one opening to allow fluid drainage out of the handle, and a mechanism,
9 the mechanism being attached to the pushing device to allow a physician to
10 control the position of the pushing device within the lumen of the connecting
11 segment and the lumen of the stent whereby moving the mechanism:
12 (i) to a first position proximally extends the pushing device resulting in the
13 release of the stent, and
14 (ii) to a second position proximally retracts the pushing device resulting in the
15 absence of the pushing device within the lumen of the stent.
- 1 19. A method of placing a prostatic stent-catheter system, comprising the steps of:
2 (a) providing the prostatic stent-catheter system which comprises:
3 (i) a stent comprising a body member including a distal terminating end, a
4 proximal end portion, and a lumen extending within the body member, the
5 body member sized for placement substantially within the prostatic section
6 of the urethra with the distal terminating end located proximal of the
7 external sphincter; and
8 (ii) a connecting segment comprising an elongated body member including a
9 distal end located outside of a patient's body, a proximal end releasably

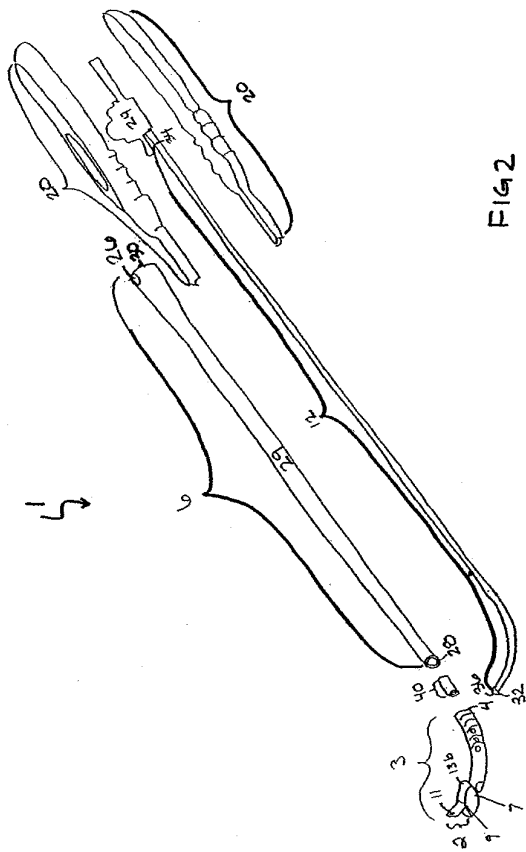
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- 10 coupled to the distal terminating end of the stent, and a lumen extending
11 within the elongated body member;
- 12 (b) inserting the prostatic stent-catheter system into the patient's urethra;
13 (c) positioning the stent substantially within the prostatic section of the urethra;
14 (d) monitoring fluid drainage through the stent and the connecting segment, and out
15 of the distal end of the connecting segment located outside of the patient's body;
16 (e) decoupling the connecting segment from the stent; and
17 (f) withdrawing the connecting segment completely from the urethra and patient's
18 body.





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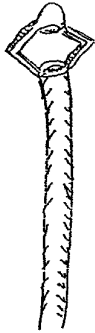


FIG. 3

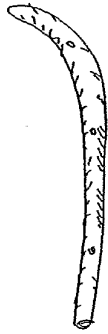
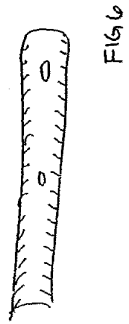
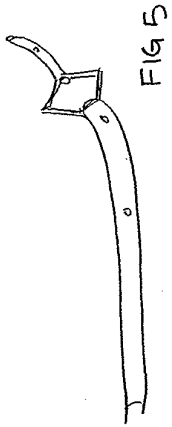


FIG. 4

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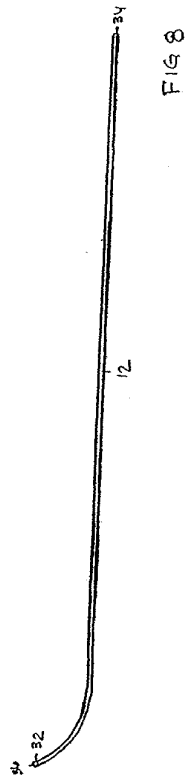
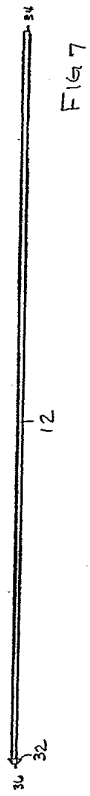
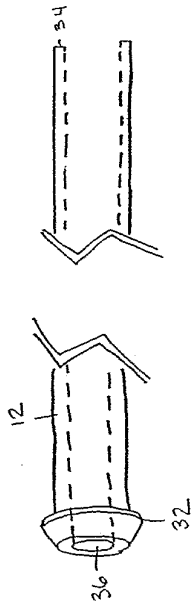
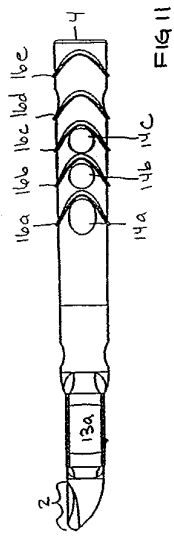
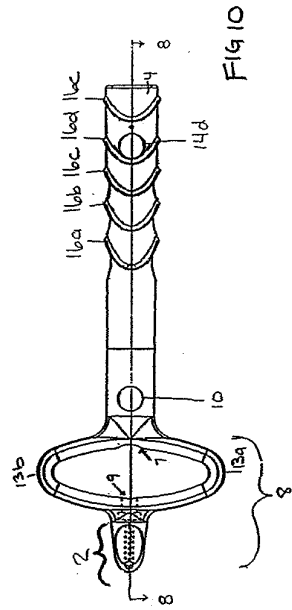


Fig 9





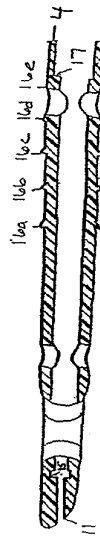
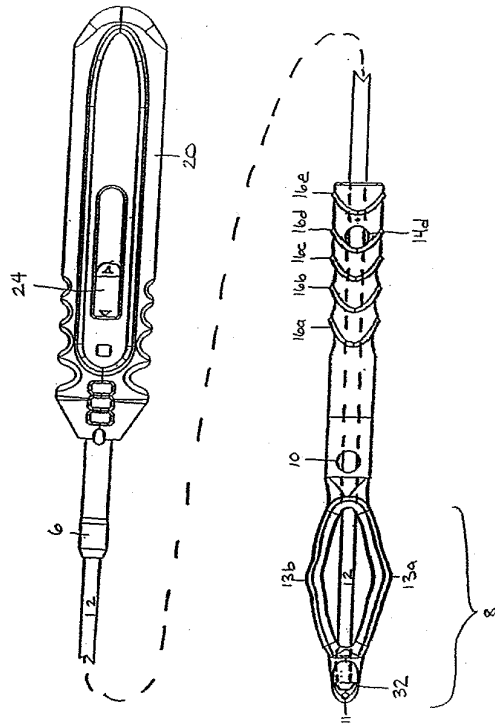


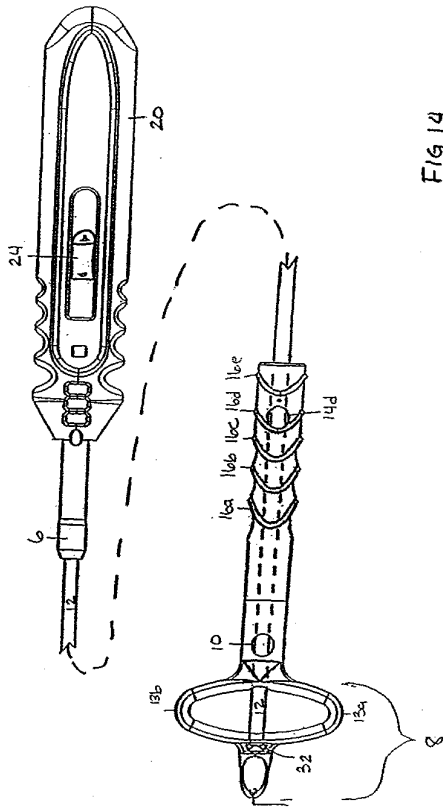
Fig. 12

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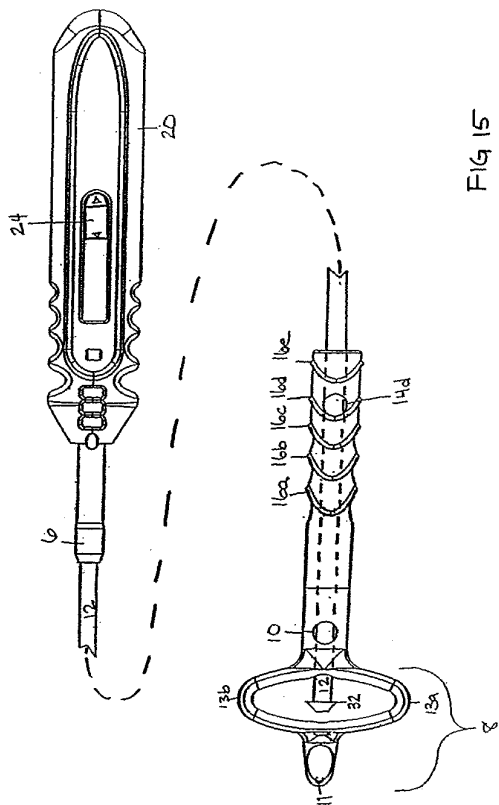
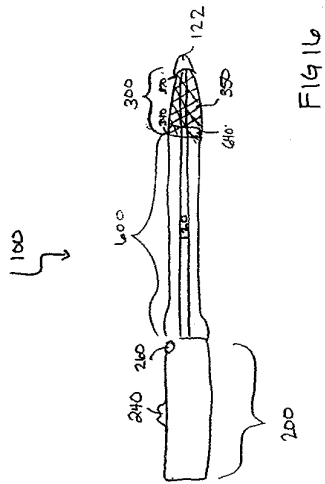


Fig 15



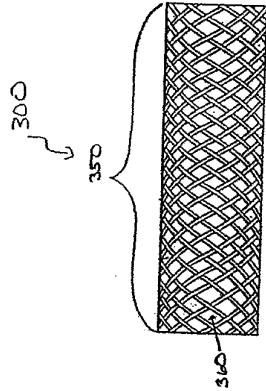


FIG 17

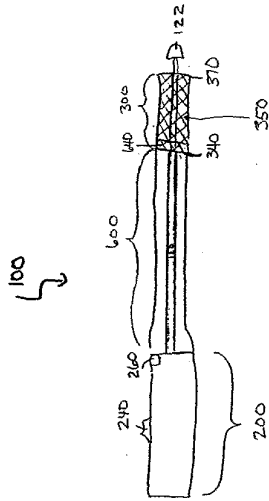
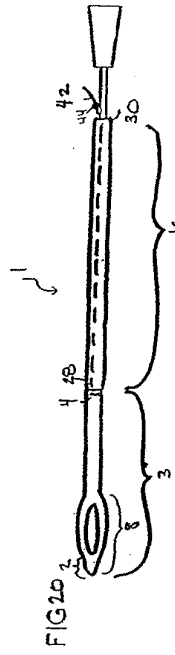
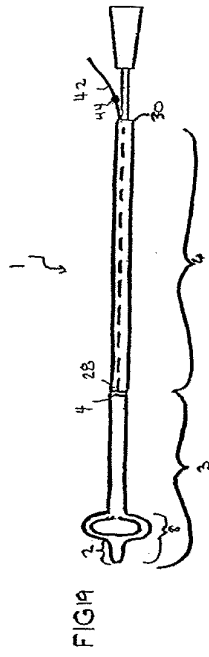
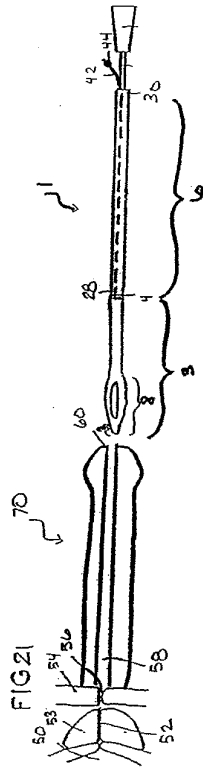
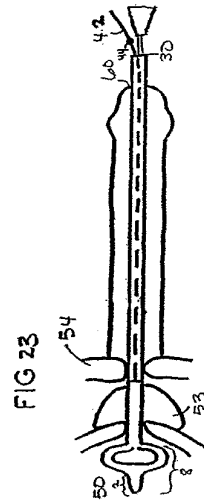
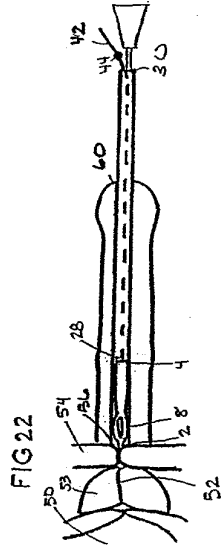
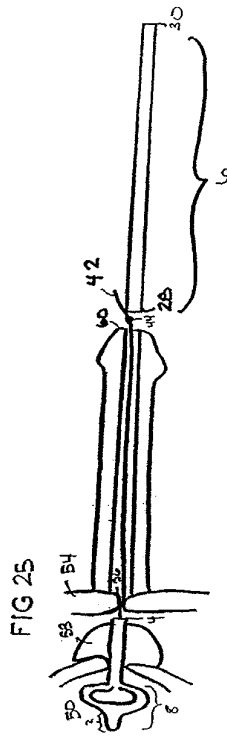
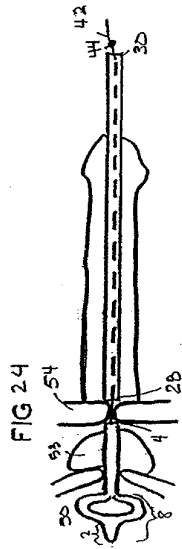


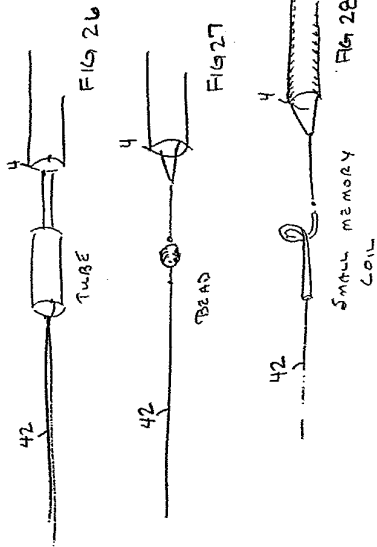
FIG 18











【国際公開パンフレット（コレクトバージョン）】

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
9 August 2001 (09.08.2001)

PCT

(10) International Publication Number
WO 01/56629 A3

(51) International Patent Classification: A61F 2/04, 2/06

(21) International Application Number: PCT/US01/03001

(22) International Filing Date: 30 January 2001 (30.01.2001)

(25) Filing Language: English

(26) Publication Language: English

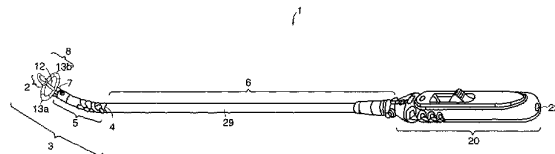
(30) Priority Data:
60/180,131 3 February 2000 (03.02.2000) US
60/188,002 9 March 2000 (09.03.2000) US
09/733,752 8 December 2000 (08.12.2000) US(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US];
One Scimed Place, Maple Grove, MN 55311-1566 (US).(72) Inventors: HAMMOND, Gaines, W.; 609 Crystal Drive,
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Pebble Brook Road, North Easton, MA 02356 (US).(74) Agent: TOSTI, Robert, J.; Testa, Hurwitz & Thibault
LLP, High Street Tower, 125 High Street, Boston, MA
02110 (US).(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ,
DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR,
HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR,
LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ,
NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM,
TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,
CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

(88) Date of publication of the international search report:
25 April 2002For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: PROSTATIC STENT FACILITATING DRAINAGE



(57) Abstract: A prostatic stent (3) comprises a body member (5) and a retaining member. The body member (5) includes a distal terminating end (4), a proximal end portion (7), and a lumen extending within the body member to allow fluid drainage through the body member. The body member (5) is sized for placement substantially within the prostatic section of the urethra, with the distal terminating end (4) located proximal of an external sphincter to allow normal operation of the external sphincter. The retaining member (8) extends from the proximal end portion (7) of the body member (5). The retaining member (8) is collapsible into a first state to allow passage of the prostatic stent (3) into the urethra, and the retaining member (8) is expandable into a second state when located in a bladder to hold the body member (5) in place substantially within the prostatic section of the urethra.

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【国際公開パンフレット（コレクトバージョン）】

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
9 August 2001 (09.08.2001)

PCT

(10) International Publication Number
WO 01/056629 A3

(51) International Patent Classification: A61F 2/04, 2/06

(21) International Application Number: PCT/US01/03001

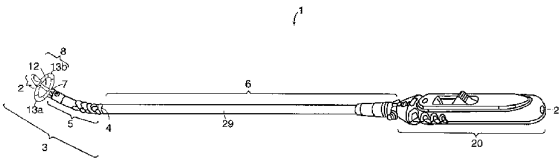
(22) International Filing Date: 30 January 2001 (30.01.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/180,131 3 February 2000 (03.02.2000) US
60/188,002 9 March 2000 (09.03.2000) US
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HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR,
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NO, NZ, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM,
TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.(84) Designated States (regional): ARIPO patent (GH, GM,
KI, LS, MW, MZ, SD, SI, SZ, TZ, UG, ZW), Eurasian
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European
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CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).Published:
— with international search report(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US];
One Scimed Place, Maple Grove, MN 55311-1566 (US).(88) Date of publication of the international search report:
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Pebble Brook Road, North Easton, MA 02356 (US).(48) Date of publication of this corrected version:
9 January 2003(74) Agent: TOSTI, Robert, J., Testa, Hurwitz & Thibault
111 P. High Street Tower, 125 High Street, Boston, MA
02110 (US).(15) Information about Correction:
see PCT Gazette No. 02/2003 of 9 January 2003, Section II(81) Designated States (national): AE, AG, AI, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ,For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: PROSTATIC STENT FACILITATING DRAINAGE



(57) Abstract: A prostatic stent (3) comprises a body member (5) and a retaining member. The body member (5) includes a distal terminating end (4), a proximal end portion (7), and a lumen extending within the body member to allow fluid drainage through the body member. The body member (5) is sized for placement substantially within the prostatic section of the urethra, with the distal terminating end (4) located proximal of an external sphincter to allow normal operation of the external sphincter. The retaining member (8) extends from the proximal end portion (7) of the body member (5). The retaining member (8) is collapsible into a first state to allow passage of the prostatic stent (3) into the urethra, and the retaining member (8) is expandable into a second state when located in a bladder to hold the body member (5) in place substantially within the prostatic section of the urethra.

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FACILITATING DRAINAGE

Cross-Reference to Related Applications

This claims priority to and the benefit of each of the following two provisional U.S. patent applications: serial number 60/180,131 filed on February 3, 2000, and serial number 60/188,002 filed on March 9, 2000.

Technical Field

5 This invention relates to facilitating drainage and, more particularly, to facilitating fluid drainage from the bladder and through the urethra of a patient.

Background Information

The prostate is a gland in the male urinary system located directly below the bladder and around the urethra. In some men, especially men over fifty years of age, the prostate can become
10 swollen or enlarged due to disease or infection. The enlarged prostate constricts the urethra causing discomfort and/or bladder outlet obstruction.

One of the known procedures for treating an enlarged prostate is thermal prostatic therapy. During thermal prostatic therapy, the prostate is heated above body temperature to remove the diseased tissue, whereby returning the prostate to normal size. Immediately after
15 treatment, however, the prostate is still swollen or enlarged due to the therapeutic trauma induced by the procedure. It may take several weeks before the treated prostate recovers and no longer inhibits bladder drainage.

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Summary of the Invention

The invention involves providing drainage of fluid from the bladder of a patient. Systems and methods of the invention typically are used after the patient has undergone prostate treatment such as thermal therapy. Systems and methods according to the invention involve converting in situ a urinary drainage catheter into an indwelling device. The device maintains the prostatic section of the urethra open and able to pass fluid while also allowing normal operation of the patient's external sphincter such that the patient has full and normal control over the retention and discharge of urine from the bladder even with the device in place within the prostatic section of the urethra.

In general, in one aspect, the invention relates to a prostatic stent. The prostatic stent comprises a body member and a retaining member. The body member includes a distal terminating end, a proximal end portion, and a lumen extending within the body member to allow fluid to drain through the body member. The directional terms proximal and distal require a point of reference. In this application, the point of reference in determining direction is in the perspective of the patient. Therefore, the term proximal will always refer to a direction that points into the patient's body, whereas distal will always refer to a direction that points out of the patient's body. The body member is sized for placement substantially within the prostatic section of the urethra. The distal terminating end is positioned proximal of an external sphincter so as to allow normal operation of the external sphincter. The retaining member extends from the proximal end portion of the body member. The retaining member is collapsible into a first state to allow the passage of the prostatic stent into the urethra in the first instance. The retaining member also is expandable into a second state when located in the bladder to hold the body member in place substantially within the prostatic section of the urethra.

Embodiments of this aspect of the invention can include the following features. The retaining member of the prostatic stent can be tapered to provide comfort to the patient during insertion of the stent into the patient's urethra. The retaining member also can comprise two or more retaining arms, and the retaining arms can be biased in the second state. Prior to and during insertion of the prostatic stent into the patient's urethra, the retaining member is in the first state. The retaining member returns to substantially the second state once in the patient's bladder and thereby acts as an anchor to keep the body member of the prostatic stent substantially within the prostatic section of the urethra. The body member of the prostatic stent can include one or more side openings to allow fluid to drain from the prostatic section of the urethra into the lumen. To

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help prevent migration of the prostatic stent, the body member also can have one or more protrusions. The protrusions are designed to engage the wall of the prostatic urethra and thereby provide a source of friction that limits the motion of the prostatic stent within the urethra. The body member also can include a suture attached to the distal terminating end. The suture should
5 be long enough to extend from the body member to the patient's meatus. The prostatic stent can be removed easily from the patient's body by pulling on the suture. The end of the suture can be connected to a ball, ring, coil, or other structure that either extends out of the body entirely or is located within the meatus. The point of the ball, ring, coil or other structure at the end of the suture is to facilitate location of the end of the suture and then removal of the stent by the patient
10 himself or by a medical professional, simply by pulling on the located suture.

In another aspect, the invention relates to a prostatic stent-catheter system for draining fluid from the bladder, through the prostatic urethra, and out of the patient's body. The prostatic stent-catheter comprises a stent and a connecting segment. The stent includes a body member comprising a distal terminating end, a proximal end portion, and a lumen extending within the
15 body member. The body member is sized for placement substantially within the prostatic section of the urethra with the distal terminating end located proximal of the external sphincter to allow normal operation of the external sphincter. The connecting segment comprises an elongated body member including a distal end, a proximal end, and a lumen. The proximal end of the connecting segment is releasably coupled to the distal terminating end of the stent. The prostatic
20 stent-catheter system has at least two modes of operation after being inserted into the patient's urethra. In a first mode, the stent and connecting segment are coupled together, and drainage of fluid from the bladder occurs continuously. In a second mode, the connecting segment is decoupled from the stent in situ, and the connecting segment then is removed from the patient's urethra. After the connecting segment is removed from the patient's body, the patient's external
25 sphincter contracts and is allowed to function normally to allow the patient have full control over voiding of urine.

Embodiments of this aspect of the invention can include the following features. The stent portion of the prostatic stent-catheter can further include a retaining member extending proximally away from the body member. When the stent-catheter system is properly positioned,
30 the retaining member will be located in the patient's bladder. In one embodiment the retaining member comprises a proximal curved tip that acts as an anchor within the bladder opening to prevent the distal migration of the stent. In another embodiment, the retaining member includes

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at least two retaining arms biased in an expanded state. The retaining arms are collapsible and are collapsed prior and during the insertion of the prostatic stent-catheter into the patient's urethra. The retaining arms in the present embodiment return to the expanded state once located in the patient's bladder and thereby act as an anchor to prevent stent migration. The contraction and the expansion of the retaining arms can be controlled through a pushing device while the prostatic stent-catheter is within the patient's body. The stent portion of the prostatic stent-catheter system can further include a body member comprising of a large pore mesh. The large pore mesh can be fabricated from any biocompatible, self-expanding material such as a nickel-titanium based alloy. The body member including the large pore mesh frictionally engages the patient's prostate, whereby anchoring the stent to prevent migration.

In general, in still another aspect, the invention relates to a method of placing a prostatic stent-catheter system within the urethra. The prostatic stent-catheter system, which includes a stent and a connecting segment releasably coupled to one another, is inserted into the urethra of the patient. A medical professional such as a physician advances the prostatic stent-catheter system through the urethra until at least a portion of the stent is positioned substantially within the prostatic section of the urethra. When properly positioned, at least a portion of the stent will reside within the prostatic section of the urethra, while the connecting segment will extend through the external sphincter, through the rest of the urethra, and outside of the patient's body. The physician will know that the prostatic stent-catheter system is properly positioned when urine or other bodily fluid is observed draining through the distal end of the connecting segment. Bodily fluids such as urine and blood draining through the prostatic stent-catheter system are monitored. If the procedure is being done after treatment (e.g., surgery) on the prostate, the medical professional must determine when the patient's prostate has recovered or is recovering sufficiently from the treatment, and then the professional decouples the connecting segment from the stent and withdraws the connecting segment entirely from the patient's body. The stent thus remains within the prostatic section of the urethra to prevent bladder outlet obstruction and to keep the prostatic section of the urethra open and passing fluid(s) from the bladder while allowing normal operation of the patient's external sphincter. Once the prostate has fully recovered and poses no risk of obstructing fluid drainage, the stent can be removed. Removal of the indwelling stent can be accomplished by pulling on a suture attached to the stent. The suture typically is left extending from the urethra outside of the patient's body, or it can be left just

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within the meatus and therefore easily located by the patient himself or a medical professional such as a doctor or nurse.

The foregoing and other objects, aspects, features, and advantages of the invention will become more apparent from the following description and from the claims.

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Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

- 5 FIG. 1 is a schematic view of a prostatic stent-catheter system according to one embodiment of the present invention.
- FIG. 2 is an exploded view of the prostatic stent-catheter system shown in FIG. 1.
- FIG. 3 is a schematic view of one embodiment of a prostatic stent.
- FIG. 4 is a schematic view of another embodiment of a prostatic stent.
- 10 FIG. 5 is a schematic view of another embodiment of a prostatic stent.
- FIG. 6 is a schematic view of another embodiment of a prostatic stent.
- FIG. 7 is a schematic view of one embodiment of a pushing device of a prostatic stent-catheter system according to the invention.
- FIG. 8 is a schematic view of another embodiment of a pushing device.
- 15 FIG. 9 is an enlarged view of the proximal end of one embodiment of a pushing device.
- FIG. 10 is an enlarged plan view of a prostatic stent.
- FIG. 11 is a side view of the prostatic stent shown in FIG. 10.
- FIG. 12 is a cross-sectional view of the prostatic stent taken along the lines 8-8 in FIG. 10.
- 20 FIG. 13 is a schematic view of both a handle mechanism in a first position and a corresponding collapsed prostatic stent configuration with an engaged pushing device.
- FIG. 14 is a schematic view of both a handle mechanism in a second position and a corresponding expanded prostatic stent configuration with an engaged pushing device.
- FIG. 15 is a schematic view of both a handle mechanism in a third position and a corresponding expanded prostatic stent configuration with a disengaged pushing device.
- 25 FIG. 16 is a plan view of another embodiment of a prostatic stent-catheter system, in an insertion configuration.
- FIG. 17 is an enlarged plan view of the prostatic stent shown in FIG. 16.
- FIG. 18 is the prostatic stent-catheter system of FIG. 16 in a release configuration.
- 30 FIG. 19 is a schematic view of the prostatic stent-catheter system of FIG. 1, showing the prostatic stent-catheter system in an expanded configuration.

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FIG. 20 is a schematic view of the prostatic stent-catheter system of FIG. 19 in an insertion configuration.

FIG. 21 is a schematic view of a male urinary system and the prostatic stent-catheter system of FIG. 20 prior to insertion.

5 FIG. 22 is a schematic view illustrating insertion of the prostatic stent-catheter system of FIG. 20.

FIG. 23 is a schematic view illustrating proper placement of the prostatic stent-catheter system of FIG. 19.

10 FIG. 24 is a schematic view illustrating connecting segment decoupling from the prostatic stent-catheter system of FIG. 19.

FIG. 25 is a schematic view illustrating connecting segment removal from the male urinary system.

FIG. 26 is an enlarged schematic view of one embodiment of a retaining device.

FIG. 27 is an enlarged schematic view of another embodiment of a retaining device.

15 FIG. 28 is an enlarged schematic view of another embodiment of a retaining device.

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Description

The invention generally relates to relieving bladder outlet obstruction. After prostate treatment, a patient can experience urinary retention. The invention generally involves treating urinary retention, especially male urinary retention, while still allowing normal operation of the patient's external sphincter (and thus allowing normal voiding of the bladder) even with a stent located temporarily within the prostatic section of the patient's urethra.

After a medical procedure to treat an obstructed prostate, such as thermal prostate therapy, a patient may experience prostate bleeding while the recently-treated prostate recovers. Another consequence of such medical procedures is bladder outlet obstruction which results from the still-slightly enlarged and recovering prostate. After the procedure, the medical professional (e.g., a physician) that performed the procedure or some other medical professional will monitor the amount of urine and prostate bleeding, and attempt to provide the patient with an open urinary passageway. In order to monitor continuously the bodily fluids from the patient's bladder and prostate, the medical professional(s) attending to the patient need to prevent the patient's external sphincter from closing to allow constant and uninterrupted drainage of those bodily fluids. In general, the attending professional(s) only need(s) to monitor the flow of blood and urine from the patient's urinary system for a few hours. It may, however, take several weeks for the patient's prostate to recover. One of the objects of the present invention is to provide devices, systems, and methods which will maintain an open passageway throughout the patient's entire urinary system such that constant drainage can be realized for some period of time just after treatment of the prostate, and which also can thereafter provide an open urinary passageway from the bladder through the prostatic section of the urethra while simultaneously allowing normal operation of the patient's external sphincter such that the patient has full and normal control over bladder voiding.

Referring to FIGS. 1 and 2, a prostatic stent-catheter system 1 of the invention comprises a prostatic stent 3 and a connecting segment 6. The prostatic stent 3 includes a body member 5 made of one or more biocompatible materials such as silicone, nylon, polyglycolic acid, or stainless steel, and sized to fit substantially within the prostatic section of the urethra. The body member 5 has a proximal end 7, a distal terminating end 4, and a lumen extending from the proximal end 7 to the distal terminating end 4 to allow fluid drainage through the body member 5. As previously mentioned in this application, the term proximal refers to a direction that points into the patient's body and the term distal refers to a direction that points out of the patient's

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body. The body member 5 may be reinforced with a wire mesh to increase the tensile strength of the prostatic stent 3 whereby decreasing the possibility of the lumen collapsing. The prostatic stent 3 as illustrated in FIGS. 1 and 2 further comprises a retaining member 8. The retaining member 8 is also made from one or more biocompatible materials. In the disclosed embodiment, the retaining member 8 has at least two retaining arms 13a and 13b. Other retaining member 8 embodiments are possible, so long as these embodiments anchor the body member 5 within the prostatic section of the urethra, and do not inhibit fluid drainage from the bladder. Examples of some other retaining members are given in FIGS. 3-6. Other further possible embodiments of retaining member shapes include umbrella shaped prongs and a pigtail curl. All retaining member embodiments must be either collapsible or able to be straighten for insertion ease. Similarly, a retaining member is not required if a prostatic stent includes another means to prevent migration of the prostatic stent from the prostatic section of the urethra (for example, a body member that frictionally engages the patient's prostate). The retaining member 8, as shown as in the embodiment of the device in FIGS. 1-2, also includes a proximal tip 2. Within the proximal tip 2, there is a lumen extending from a base proximal tip opening 9 to a proximal tip opening 11. The retaining member 8 is collapsible and has at least two distinct states. In a first state, the retaining member 8 is collapsed to allow for insertion ease. In a second state, the retaining member 8 is expanded to secure the prostatic stent 3 from significant migration after the prostatic stent 3 has been properly positioned. The prostatic stent 3 is properly positioned within a male patient's urinary system, when the retaining member 8 is located within the patient's bladder and the body member 5 is located substantially within the prostatic section of the urethra with the distal terminating end 4 being located proximal to the patient's external sphincter. The connecting segment 6 of the prostatic stent-catheter system 1 comprises an elongated body member 29 having a proximal end 28 and a distal end 30. A lumen extends from the proximal end 28 to the distal end 30 for fluid drainage. At the distal end 30 of the connecting segment 6 there is at least one side opening 26 for fluid drainage.

During insertion of the prostatic stent-catheter system 1, the proximal end 28 of the connecting segment 6 is releasably coupled to the distal terminating end 4 of the prostatic stent 3. The coupling of the prostatic stent 3 with the connecting segment 6 creates a single lumen extending from the proximal end 7 of the body member 5 to the distal end 30 of the connecting segment 6. To couple the prostatic stent 3 to the connecting segment 6 a guide 40 is used. The guide 40 is an open ended tubular body member having a slightly smaller diameter than both the

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connecting segment 6 and the body member 5. The guide 40 is fastened to the proximal end 28 of the connecting segment 6 such that a portion of the guide 40 is within the lumen of the connecting segment 6 and the remaining portion extends out from the proximal end 28 of the connecting segment 6. The remaining portion of the guide 40 is then inserted into the lumen of the body member 5 creating a slip-fit seal between the prostatic stent 3 and the connecting segment 6. Various other couplings are possible, so long as the distal terminating end 4 of the body member 5 and the proximal end 28 of the connecting segment 6 are releasably joined together. For example, in other embodiments, the guide 40 is releasably coupled to the prostatic stent 3 with sutures that can be removed in situ after the prostatic stent 3 is properly positioned.

After a prostatic procedure to treat an obstructed prostate, such as thermal therapy, the patient's prostate typically will still be slightly enlarged and it may bleed. To prevent bladder obstruction and to monitor the amount of urine production and prostate bleeding, a physician can insert the prostatic stent-catheter 1 into a patient's urethra until the proximal tip 2 is located within the bladder and the connecting segment 6 extends through the external sphincter as to allow constant drainage of fluids from the patient's bladder and through the patient's prostate. Once the physician has decided that the patient's bodily fluids no longer need to be monitored, constant fluid drainage from the patient's bladder is no longer necessary. To avoid the potential risk of bladder retention due to the slightly enlarged and recently treated prostate, however, the physician may wish to maintain the prostatic stent 3 within the prostatic section of the urethra until the prostate is completely resolved. The physician, realizing that patient's prostate could take several weeks to resolve and not wishing to inconvenience the patient, can remove the connecting segment 6 from the prostatic stent-catheter system 1 while leaving the prostatic stent 3 in place by simply pulling on the connecting segment 6.

The embodiment of the prostatic stent-catheter system 1 of FIGS. 1 and 2 further comprises a pushing device 12 and a handle 20. The pushing device 12 has a proximal end 36 and a distal end 34. The width of the pushing device 12 is sized to fit within the lumens of the prostatic stent 3 and the connecting segment 6; while the length of the pushing device 12 is sized so that the proximal end 36 can contact the proximal tip 2 of the prostatic stent 3 while the distal end 34 extends beyond the distal end 30 of the releasably connected connecting segment 6. Therefore, the physician performing the procedure can use the pushing device 12 to contact the proximal tip 2 of the prostatic stent 3 once the prostatic stent-catheter system 1 is already inserted into the patient's body. The pushing device 12 can be made from any material that is flexible

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enough to conform to the patient's anatomy, but also rigid enough to extend the proximal tip 2 away from the body member 5. Materials such as stainless steel or polycarbonate meet these criteria. The pushing device 12 can be either straight as shown in FIG. 7 or curved as shown in FIG. 8, to aid in the insertion and placement of the prostatic stent 3 within the prostatic section of the urethra. Extending through the entire pushing device 12 is a lumen capable of receiving a guide wire. At the proximal end 36 of the pushing device 12 is a flange 32 used to connect the proximal tip 2 to the pushing device 12. The flange 32 also prevents premature separation of the pushing device 12 from the proximal tip 2. The flange 32 is best illustrated in FIG. 9. The other end of the pushing device, the distal end 34, is attached to a mechanism 24 located within the handle 20. The mechanism 24 is slidably movable in the proximal and distal directions. Because the mechanism 24 is attached to the pushing device 12, the position of the mechanism 24 determines the position of the pushing device 12 within the prostatic stent-catheter system 1. The handle 20 is attached to the distal end 30 of the connecting segment and remains outside of the patient's body. Therefore, a physician has access to the position of the pushing device 12 at all times during a procedure. Besides the mechanism 24, the handle 20 also includes at least one opening 22 for drainage of fluids from the prostatic stent-catheter system 1.

The embodiment of the prostatic stent 3 of FIGS. 1 and 2 includes a series of openings 10, 14a - 14d in communication with the lumen of the body member 5, and a series of protuberances 16a - 16e. These features are most clearly illustrated in FIGS. 10-12. The series of openings 10, 14a-14d and/or the series of protuberances 16a-16e on the body member 5 decrease the likelihood of migration of the prostatic stent 3. The protuberances may be parallel to each other or may be progressively angled to further decrease migration. In the disclosed embodiment, the series of protuberances 16a - 16e have a serpentine pattern, however other possible patterns such as circular or spiral are possible. When the prostatic stent 3 is properly positioned, the series of protuberances 16a-16e are in contact with the patient's prostate. Consequently, the series of protuberances 16a - 16e create a source of friction between the prostatic stent 3 and the prostate which decreases movement of the prostatic stent 3. The series of openings 10, 14a-14d in the body member 5 also create friction between the patient's prostate and the prostatic stent 3. The series of openings 10, 14a- 14d further allow bodily fluids such as urine or blood to enter into the body member 5 of the prostatic stent 3 while permitting prostate tissue to extend into the prostatic stent 3 to aid in securing the prostatic stent 3 from migrating. To further prevent migration, the distal terminating end 4 may be belled outward to a diameter

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larger than the body member 5 but essentially equal to the connecting segment 6. FIG. 12 is a cross sectional view of the prostatic stent 3. In this drawing a proximal ledge 15 and a distal ledge 17 are noticeable in the internal prostatic stent 3 profile. The proximal ledge 15 is designed to receive the flange 32 of the pushing device 12 (shown in FIG. 9). The proximal ledge 15 provides a contact surface for the flange 32 to push against when the pushing device 12 is proximally extended. The distal ledge 17 is designed to receive the guide 40 (shown in FIG. 2). The distal ledge 17 provides a contact surface for the guide 40 to rest against while the prostatic stent 3 and the connecting segment 6 are coupled together.

As previously discussed, the prostatic stent 3 as illustrated in FIGS. 1 and 2 includes a retaining member 8 with at least two distinct states. The retaining member 8 is biased in the second state. The physician can change the retaining member's 8 configuration to the collapsed or first state by either applying pressure with his or her fingers to the retaining arms 13a - 13b to extend the proximal tip 2 in the proximal direction and thus collapse the retaining member 8 or by proximally extending the pushing device 12 within the lumen of the prostatic stent-catheter system 1 to extend the proximal tip 2 and thereby collapse the retaining member 8. In the latter case, the physician can control the process from outside of a patient's body by placing the mechanism 24 into a first position causing the extension of the pushing device 12. This process is schematically illustrated in FIG. 13. Similarly, the retaining member 8 can be returned to the second state by either removing the pressure on the retaining member 8 or retracting the pushing device 12 within the prostatic stent-catheter system 1. FIG. 14 shows the expansion of the retaining member 8 as a result of placing the mechanism 24 in a second position. To detach the pushing device 12 from the prostatic stent 3, the mechanism 24 is placed into a third position, shown in FIG. 15.

Another embodiment of a prostatic stent-catheter system 100 is illustrated in FIG. 16.

The prostatic stent-catheter system 100 comprises a prostatic stent 300 and a connecting segment 600. The prostatic stent 300 includes a large pore mesh design 350, a proximal end 370, a distal end 340, and a lumen extending between the proximal end 370 and the distal end 340. An enlarged view of the large pore mesh design 350 is illustrated in FIG. 17. The large pore mesh 350 is fabricated from any self-expanding, biocompatible material such as nylon, polyglycolic acid, stainless steel or nickel-titanium based alloys. The large pore mesh 350 is produced by weaving, braiding, or heat bonding strands of the selected self-expanding, biocompatible materials together or by slotting or pattern cutting by laser and/or conventional machining a

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hollow tube of the selected material. The large pore mesh 350 may be coated with a thin polymeric layer to prevent trauma to the patient's urethra during insertion. Each pore 360 in the large pore mesh is an opening for fluids to drain into the lumen of the prostatic stent 300.

Because the prostatic stent 300 includes many pores, the possibility of all of the pores 360 becoming blocked by blood clots so as to inhibit drainage is small. The prostatic stent 300 is sized to fit within the prostatic section of the urethra. When properly positioned the proximal end 370 is located distal to the bladder while the distal end 340 terminates proximal to the external sphincter. In the disclosed embodiment, the prostatic stent 300 has a circular cross section. The shape of the cross section need not be circular. In other embodiments, a prostatic stent including a large pore mesh can have other cross sectional shapes such as a triangle or oval. In still yet other embodiments, the shape of a prostatic stent could differ from the disclosed embodiment by having a non-constant cross sectional shape such as hourglass or funnel shapes.

The prostatic stent-catheter system 100 of the embodiment illustrated in FIG. 16 further includes a guide 640 for coupling the prostatic stent 300 to the connecting segment 600, a handle 200 including an activation mechanism 240 and openings for fluid drainage 260, and a pushing device 120. The pushing device has a bullet-shaped proximal end 122. The bullet-shaped proximal end 122 is capable of capturing and collapsing the proximal end 370 of the prostatic stent 300. The opposite end of the pushing device is attached to the activation mechanism 240 in the handle 200. FIG. 18 illustrates the prostatic stent-catheter system 100 in a release configuration. The physician performing the procedure can achieve the release configuration by extending the pushing device 120 so that the bullet-shaped proximal end 122 releases the proximal end 370 of the prostatic stent 300. The physician can then remove the connecting segment 600 from the prostatic stent-catheter system 100 by decoupling the connecting segment 600 from the prostatic stent 300, and removing the connecting segment 600, the handle 200, and pushing device 120 from the patient's urethra.

The prostatic stent-catheter system 100 illustrated in FIG. 16 is placed into the patient's body, used in the patient's body, and removed from the patient's body in the same way that the other embodiments of prostatic stent-catheter systems described herein are placed, used, and removed.

The prostatic stent-catheter system 1 in FIGS. 19-25 is of the embodiment illustrated in FIGS. 1 and 2. In this embodiment, the prostatic stent 3 further comprises a retaining member 8 as previously described. In FIG. 19, the prostatic stent 3 in this invention is in its biased or

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natural state. The prostatic stent-catheter system 1 in FIGS. 19-25 further includes at least one suture 42. In another embodiment, the suture 42 can be replaced with any tubular structure that is thin enough to pass through the external sphincter 54 without negatively impacting the operation of the external sphincter 54 such as a long membrane. The suture 42 or tubular structure can be useful when removing the prostatic stent 3 from the prostatic section of the urethra at some point after the prostate has resolved. To attach the suture 42 to the prostatic stent 3 one end of the suture 42 is threaded through the distal terminating end 4 of the prostatic stent 3. The suture 42 is intended to run parallel to the prostatic stent 3 and connecting segment 6 walls along the lumen to reduce the likelihood of catching and holding blood clots. The other end of the suture 42 can be attached or connected to a retaining device 44. The retaining device 44 serves as a recovery means if the prostatic stent 3 proximally migrates. The retaining device 44 is slidably adjustable along the entire length of the suture 42, thereby allowing the physician to be able to position the retaining device 44 either within or external to the meatus 60. In the disclosed embodiment, the retaining device 44 is located external to the meatus 60 to permit erections. The retaining device 44 in FIGS. 19-25 is a bead. Various other embodiments of retaining devices are possible. Some of the other possible embodiments of retaining devices are illustrated in FIGS. 26-28.

Before a physician can insert the prostatic stent-catheter system 1 including a retaining member 8, the retaining member 8 must be collapsed. FIG. 20 shows a prostatic stent-catheter system 1 of a disclosed embodiment in an insertion or collapsed configuration. FIGS. 21-23 illustrate a method of inserting and placing a prostatic stent-catheter system 1. The remaining drawings, FIGS. 24-25 depict the decoupling of the prostatic stent 3 and the connecting segment 6 and the subsequent removal of the connecting segment 6 from a patient's urethra.

FIG. 21 shows an illustration of both the prostatic stent-catheter system 1 in the insertion configuration (i.e., collapsed retaining member), and a male urinary system 70. The male urinary system 70 including a urethra 58, an external sphincter 54, an opening to the external sphincter 56, a prostate 53, a prostatic section of the urethra 52, and a bladder 50. The point of insertion of the prostatic stent-catheter system 1 is the meatus 60.

To position the prostatic stent-catheter system 1 within a patient to relieve bladder outlet obstruction and to monitor a patient's bodily fluid excretions (post thermal prostate therapy, for example), a physician inserts the prostatic stent-catheter system 1 into a patient's urethra 58 through the meatus 60. This procedure is schematically illustrated in FIG 22. The prostatic

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stent-catheter system 1 is advanced through the urethra until the prostatic stent 3 is substantially within the prostatic section of the urethra 52 with the retaining member 8 residing in the bladder 50. The physician can confirm proper placement of the prostatic stent-catheter system 1 by observing urine flowing through the connecting segment 6. FIG. 23 illustrates schematically the proper placement of a prostatic stent-catheter system 1.

The prostatic stent-catheter system 1 remains inside the male urinary system 70 until a decrease in prostate bleeding is observed and a physician decides that it is no longer necessary to monitor a patient's bodily fluid excretions. Even though a patient's bodily fluid excretions no longer require monitoring, the patient's prostate 53 may still be obstructed. To prevent bladder outlet obstruction and to promote prostate 53 recovery, a physician may decide to leave the prostatic stent 3 in position, and to remove only the connecting segment 6 portion of the prostatic stent-catheter system 1. To remove the connecting segment 6, the physician first decouples the prostatic stent 3 and connecting segment 6 by pulling on the connecting segment 6 (FIG. 24). The physician is then able to withdraw the connecting segment 6 from the urethra 58 (FIG. 25). Once the connecting segment 6 portion of the prostatic stent-catheter system 1 is removed, the patient's external sphincter opening 56 contracts, allowing the external sphincter to operate normally and thus allowing the patient to control all bladder functions even though the prostatic stent 3 remains in place. The suture 42 attached to the prostatic stent 3 extends from the distal terminating end 4 through the urethra 58 and terminates just outside the meatus 60. The suture 42 is thin enough to pass through the contracted external sphincter opening 56 without negatively impacting the operation of the external sphincter or therefore the patient's bladder control. The removal of a prostatic stent 3 may be performed separately at some later time, by either pulling on the suture 42 or through endoscopic means.

Variations, modifications, and other implementations of what is described herein will occur to those of ordinary skill in the art without departing from the spirit and the scope of the invention. The invention is not to be limited by the preceding illustrative description.

What is claimed is:

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Claims

- 1 1. A prostatic stent, comprising:
 - 2 (a) a body member including a distal terminating end, a proximal end portion, and a
 - 3 lumen extending within the body member, the body member sized for placement
 - 4 substantially within the prostatic section of the urethra with the distal terminating
 - 5 end located proximal of an external sphincter; and
 - 6 (b) a retaining member extending from the proximal end portion of the body member,
 - 7 the retaining member being collapsible and expandable.
 - 1 2. The device of claim 1 wherein a proximal portion of the retaining member is
 - 2 tapered.
 - 1 3. The device of claim 1 wherein the retaining member is formed integrally with the
 - 2 body member.
 - 1 4. The device of claim 1 wherein the retaining member is biased in an expanded
 - 2 state.
 - 1 5. The device of claim 1 wherein the retaining member comprises at least two arms
 - 2 biased in the expanded state.
 - 1 6. The device of claim 1 wherein the body member comprises at least one side
 - 2 opening in communication with the lumen.
 - 1 7. The device of claim 1 wherein the body member includes at least one protrusion
 - 2 to aid retention of the body member substantially within the prostatic section of
 - 3 the urethra.
 - 1 8. The device of claim 1 wherein the body member comprises a flexible, compliant
 - 2 material capable of maintaining the lumen when located within the urethra.
 - 1 9. The device of claim 1 further comprising a suture extending from the medical
 - 2 device through the urethra, and terminating externally of the meatus to allow
 - 3 removal of the medical device from the urethra by pulling the suture.
 - 1 10. A prostatic stent-catheter system for draining fluid from the bladder and through
 - 2 the prostate after prostate treatment, comprising:

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- 3 (a) a stent comprising a body member including a distal terminating end, a proximal
4 end portion, and a lumen extending within the body member, the body member
5 sized for placement substantially within the prostatic section of the urethra with
6 the distal terminating end located proximal of the external sphincter; and
7 (b) a connecting segment comprising an elongated body member including a distal
8 end located outside of a patient's body, a proximal end releasably coupled to the
9 distal terminating end of the stent, and a lumen extending within the elongated
10 body member.
- 1 11. The prostatic stent-catheter system according to claim 10 wherein the stent further
2 comprises a retaining member extending from the proximal end portion of the
3 body member, the retaining member capable of holding the body member
4 substantially within the prostatic section of the urethra.
- 1 12. The prostatic stent-catheter system according to claim 10 wherein the stent further
2 comprises a retaining member extending from the proximal end portion of the
3 body member, the retaining member being collapsible and expandable.
- 1 13. The prostatic stent-catheter system according to claim 12 further comprising:
2 (a) a pushing device slidably receivable by the prostatic stent-catheter system, the
3 pushing device including an insertion end and an external end, the pushing device
4 sized to allow the insertion end to contact the proximal end portion of the stent
5 while the external end remains outside the patient's body; and
6 (b) a handle secured to the distal end of the connecting segment, the handle including
7 at least one opening to allow fluid drainage out of the handle, and a mechanism,
8 the mechanism being attached to the pushing device to allow a physician to
9 control the position of the pushing device within the lumen of the connecting
10 segment and the lumen of the stent.
- 1 14. The handle according to claim 13 wherein moving the mechanism:
2 (a) to a first position proximally extends the pushing device resulting in the collapse
3 of the retaining member of said stent,
4 (b) to a second position proximally retracts the pushing device resulting in the
5 expansion of the retaining member of said stent, and

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- 6 (c) to a third position proximally retracts the pushing device resulting in the absence
7 of contact between the pushing device and the proximal end portion of said stent.
- 1 15. The pushing device according to claim 13 wherein the insertion end is straight.
- 1 16. The pushing device according to claim 13 wherein the insertion end is curved.
- 1 17. The prostatic stent-catheter system according to claim 10 wherein the stent further
2 includes a self-expanding, biocompatible material and a large pore mesh design.
- 1 18. The prostatic stent-catheter system according to claim 17 further comprising:
- 2 (a) a pushing device slidably receivable by the prostatic stent-catheter system, the
3 pushing device including an insertion end and an external end, the insertion end
4 being able to restrain the proximal end portion of the stent, the pushing device
5 sized to allow the insertion end to restrain the proximal end portion of the stent
6 while the external end remains outside the patient's body; and
- 7 (b) a handle secured to the distal end of the connecting segment, the handle including
8 at least one opening to allow fluid drainage out of the handle, and a mechanism,
9 the mechanism being attached to the pushing device to allow a physician to
10 control the position of the pushing device within the lumen of the connecting
11 segment and the lumen of the stent whereby moving the mechanism:
- 12 (i) to a first position proximally extends the pushing device resulting in the
13 release of the stent, and
- 14 (ii) to a second position proximally retracts the pushing device resulting in the
15 absence of the pushing device within the lumen of the stent.
- 1 19. A method of placing a prostatic stent-catheter system, comprising the steps of:
- 2 (a) providing the prostatic stent-catheter system which comprises:
- 3 (i) a stent comprising a body member including a distal terminating end, a
4 proximal end portion, and a lumen extending within the body member, the
5 body member sized for placement substantially within the prostatic section
6 of the urethra with the distal terminating end located proximal of the
7 external sphincter; and
- 8 (ii) a connecting segment comprising an elongated body member including a
9 distal end located outside of a patient's body, a proximal end releasably

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- 10 coupled to the distal terminating end of the stent, and a lumen extending
11 within the elongated body member;
- 12 (b) inserting the prostatic stent-catheter system into the patient's urethra;
13 (c) positioning the stent substantially within the prostatic section of the urethra;
14 (d) monitoring fluid drainage through the stent and the connecting segment, and out
15 of the distal end of the connecting segment located outside of the patient's body;
16 (e) decoupling the connecting segment from the stent; and
17 (f) withdrawing the connecting segment completely from the urethra and patient's
18 body.

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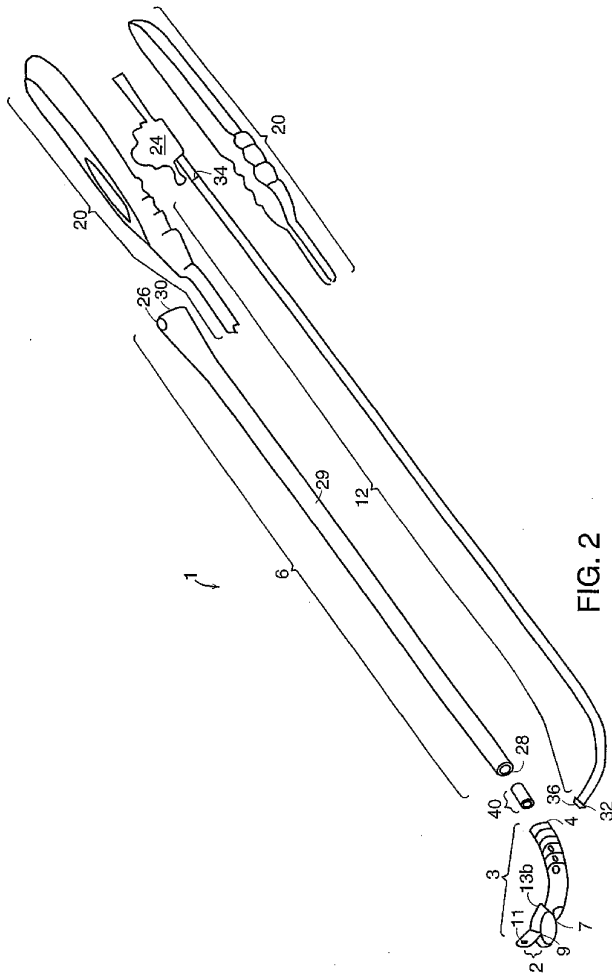
FIG. 1

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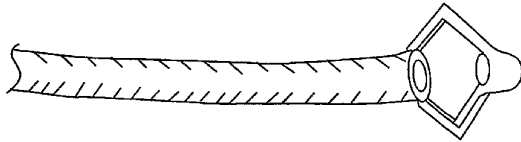


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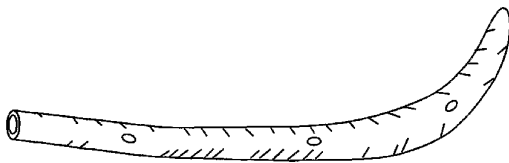


FIG. 4

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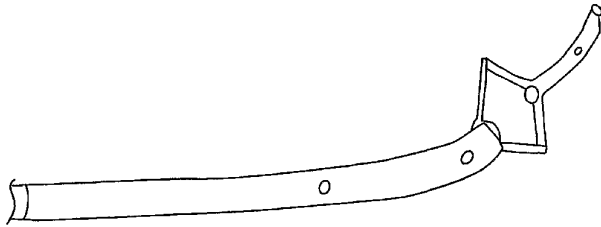


FIG. 5

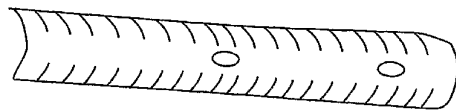


FIG. 6

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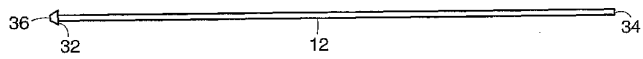


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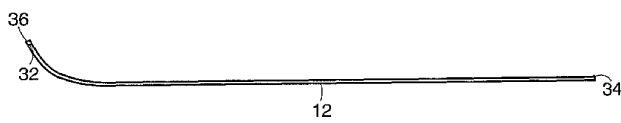
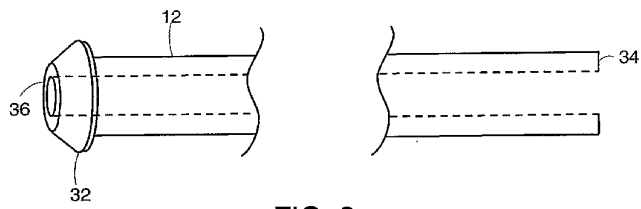


FIG. 8

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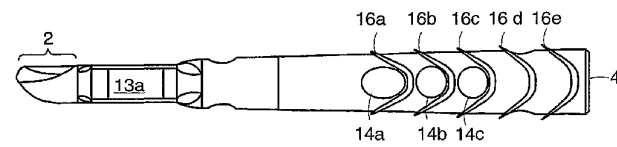
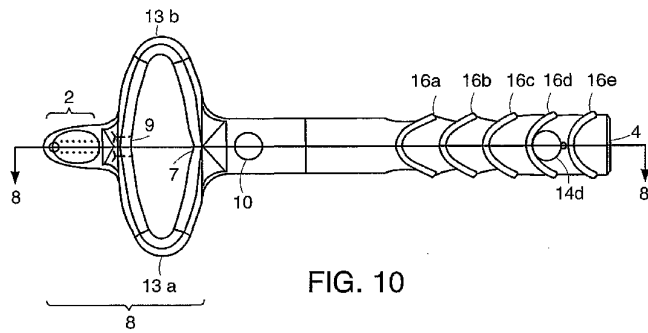


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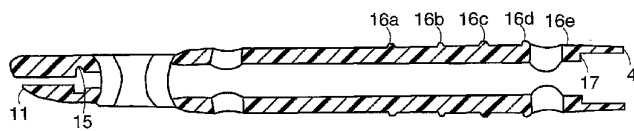


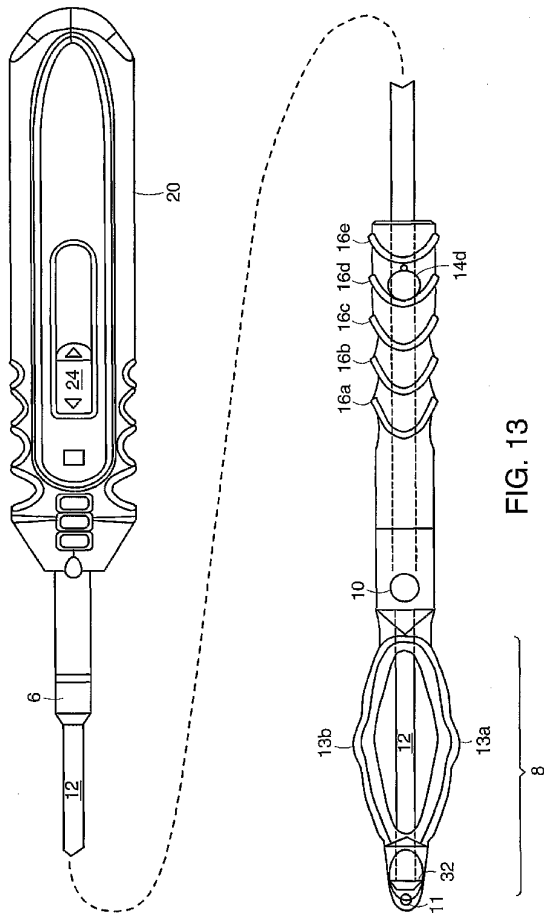
FIG. 12

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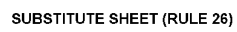
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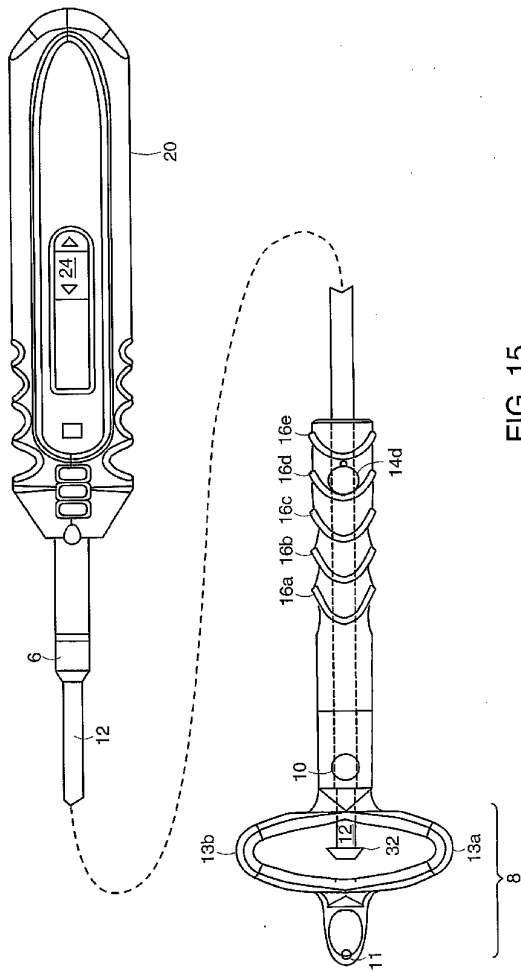
FIG. 14



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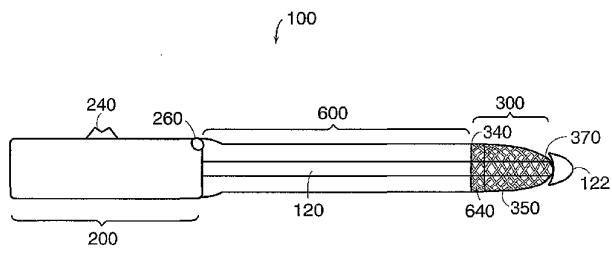


FIG. 16

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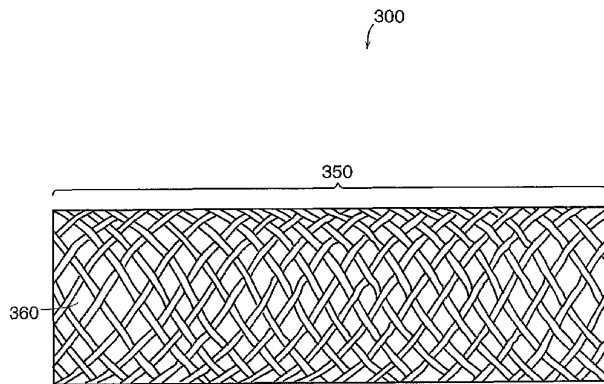


FIG. 17

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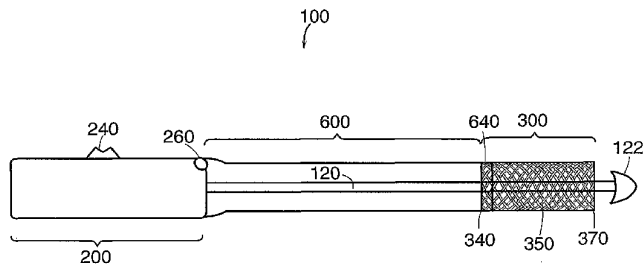


FIG. 18

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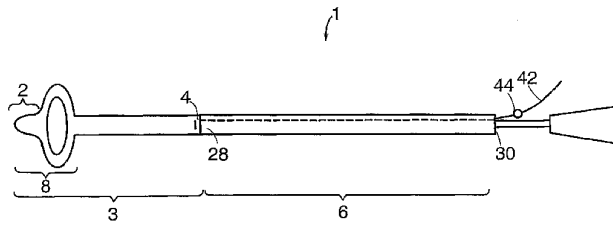


FIG. 19

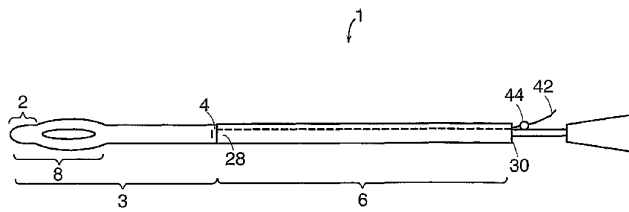


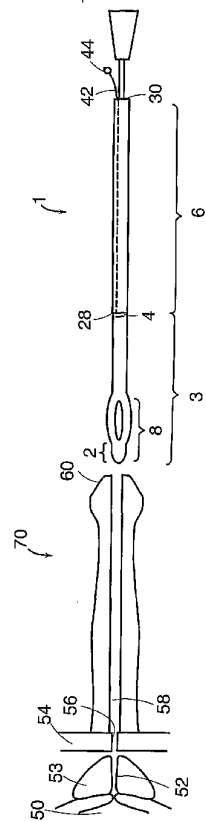
FIG. 20

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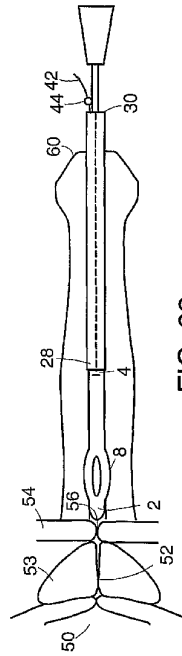


FIG. 22

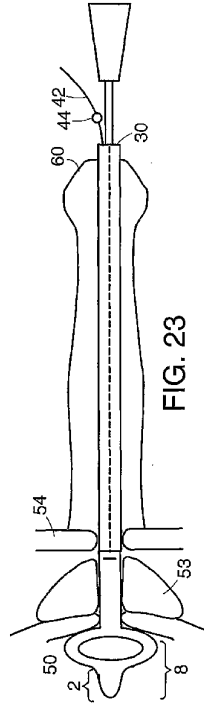


FIG. 23

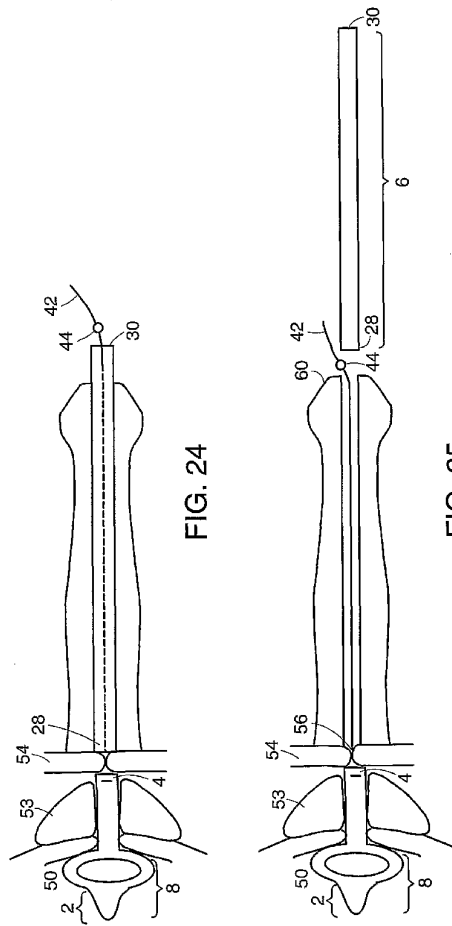
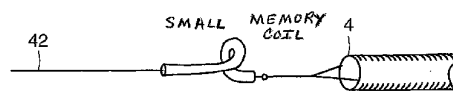
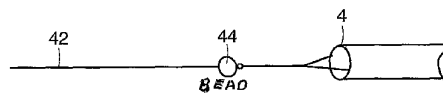
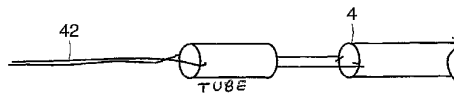


FIG. 24

FIG. 25

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【国際調査報告】

INTERNATIONAL SEARCH REPORT		International Application No. PCT/US 01/03001
A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61F2/04 A61F2/06		
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) IPC 7 A61F A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) WPI Data, PAJ, EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 041 092 A (BARWICK CARL) 20 August 1991 (1991-08-20) column 3, line 56 - column 4, line 25 column 7, line 5 - line 11 column 7, line 35 - line 42 claims; figures 1-3 -----	1-8
☐ Further documents are listed in the continuation of box C. ☒ Patent family members are listed in annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "A" document member of the same patent family		
Date of the actual completion of the international search 4 September 2001		Date of mailing of the international search report 12.02.02
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 LV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Kuehne, H-C

Form PCT/ISA/210 (second sheet) (July 1993)

INTERNATIONAL SEARCH REPORT		International application No. PCT/US 01/03001
Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)		
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:		
1.	☒ Claims Nos.: 19 because they relate to subject matter not required to be searched by this Authority, namely: Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy	
2.	☐ Claims Nos.: because they relate to parts of the international Application that do not comply with the prescribed requirements to such an extent that no meaningful international Search can be carried out, specifically:	
3.	☐ Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).	
Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)		
This International Searching Authority found multiple inventions in this international application, as follows:		
see additional sheet		
1.	☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.	
2.	☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.	
3.	☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:	
4.	☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-8	
Remark on Protest		
☐ The additional search fees were accompanied by the applicant's protest.		
☐ No protest accompanied the payment of additional search fees.		

International Application No. PCT/US 01/03001

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-8

A prostatic stent comprising a body member sized for placement within the prostatic section of the urethra and retaining member collapsible and expandable and comprising at least two arms biased in expanded state.

2. Claims: 1, 9

A prostatic stent comprising a body member sized for placement within the prostatic section of the urethra and retaining member collapsible and expandable and comprising a suture extending from the medical device to allow removal from urethra by pulling the suture.

3. Claims: 10-16

A prostatic stent system for draining fluid from bladder comprising

- a) a stent body member sized for placement within the prostatic section of the urethra,
- b) a retaining member,
- c) a connecting segment,
- d) a pushing device,
- e) a handle for allowing fluid drainage and controlling position of the pushing device.

4. Claims: 10, 17, 18

A prostatic stent system for draining fluid from bladder comprising

- a) a stent body member sized for placement within the prostatic section of the urethra,
 - b) a retaining member,
 - c) a connecting segment,
- wherein the stent includes a self-expanding, biocompatible material and a large pore mesh design.

INTERNATIONAL SEARCH REPORT
 Information on patent family members

 International Application No.
 PCT/US 01/03001

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5041092 A	20-08-1991	AU 634806 B2	04-03-1993
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フロントページの続き

(81)指定国 AP(GH,GM,KE,LS,MW,MZ,SD,SL,SZ,TZ,UG,ZW),EA(AM,AZ,BY,KG,KZ,MD,RU,TJ,TM),EP(AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE,TR),OA(BF,BJ,CF,CG,CI,CM,GA,GN,GW,ML,MR,NE,SN,TD,TG),AE,AG,AL,AM,AT,AU,AZ,BA,BB,BG,BR,BY,BZ,CA,CH,CN,CR,CU,CZ,DE,DK,DM,DZ,EE,ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KP,KR,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,MZ,NO,NZ,PL,PT,RO,RU,SD,SE,S G,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW

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アメリカ合衆国・マサチューセッツ・02356・ノース・イーストン・ペブル・ブルック・ロード・19

Fターム(参考) 4C077 AA19 DD19 DD21 EE04
4C167 AA42 BB02 BB22 CC26