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(54) **A medical guide wire**

Medizinischer Führungsdraht

Fil de guidage medical

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- **PATENT ABSTRACTS OF JAPAN vol. 1997, no. 07, 31 July 1997 (1997-07-31) & JP 09 056822 A (ASAHI INTEC KK), 4 March 1997 (1997-03-04)**

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Description

[0001] The invention relates to a medical guide wire used upon introducing a catheter into a cardiovascular system or the like.

[0002] A medical guide wire, in the form of a flexible line wire, is disclosed in Japanese Provisional Publication No. 4-25024 to ensure a safety insertion for a catheter when inserting a balloon catheter into a blood vessel to treat a diseased area such as angiostenosis of the coronary artery or when inserting a thin flexible catheter into the blood vessel for an angiography.

[0003] Japanese Laid-open Patent Application No. 3-60674 discloses a medical guide wire in which a core shaft has a ball-like head portion to engage with an open end section of a catheter to prevent its forward movement. The ball-like head portion has an advantage that enables a manipulator to withdraw the guide wire together with the catheter.

[0004] As shown in Fig. 15, the medical guide wire 30 is in the form of a flexible thin line having a main wire portion 31, and inserted from its front distal portion 32 into a complicatedly twisted, turned or bifurcated blood vessel while pushing, pulling and turning a handling knob 33 placed ouside a patient. This requires highly improved mechanical properties for the medical guide wire 30. It is especially indispensable for a front end portion 30A to have a high flexibilty and restoring force enough to return back from the deformation because the front end portion 30A plays a leading part to introduce the medical guide wire 30 into the vascular tract. For this reason, a head plug 35 is fixed to a tip of a thin core line 34, and a front portion of a helical spring 36 is provided around the core line 34 to be soldered to the head plug 35. As an alternative, a molten solder attached to the core line 34 and the helical spring 36 to form the head plug 35 is presented as a main stream structure.

[0005] In the medical guide wire 30 in which the helical spring 36 is soldered to the head plug 35, a molten soldering material inevitably adheres to the helical spring 36 and clogs a clearance 37 between line element turns of the helical spring 36 due to dispersion and sputter caused from a capillary phenomenon of the molten soldering material during the soldering operation. For this reason, a rigid 30B portion appears to extend approximately by 1.5 mm from a top of the head plug 35 to a distal end of the helical spring 36 as shown at L5.

[0006] Meanwhile, upon inserting the medical guide wire 30 into a blood vessel 37 (Fig. 16) to introduce its leading portion 32 to a diseased area such as, for example, an angiostenosis area P, whether or not a manipulator should advance the leading portion 32 is judged after confirming that the leading portion 32 is normally inserted into a true lumen (intrinsic vascular tract lumen) safely enough to pierce the diseased area by visually confirming the leading portion 32 on a monitored image and a finger tip feeling information transmitted when a manipulator pushes, pulls and turns the handling knob 33. In this instance, the leading portion 32 transmits to the handling knob 33 that there is a difference in resistance between a central hard tissue of the angiostenosis area P and an inner wall of the normal intima 38 as the information of scratching and scraggy feelings. The feelings transmitted to the handling knob 33 is a clue formation to decide whether or not the leading portion 32 is normally in the true lumen to be further advanced.

[0007] In the prior structure, due to the extended rigid portion, the leading portion lacks a flexibility which fails to transmit an exact feeling information so that the leading portion 32 may be led astray into a false lumen by pentrating through the intima 38 to reach the media 39 of the vascular tract. Once led astray into the false lumen, the leading portion 32 has a danger of piercing through the adventitial coat 40 out of the vascular tract, and the manipulator will find it difficult to return the leading portion 32 back to the true lumen as well as to exlore a new route back to the true lumen. This becomes a great hindrance to treating and curing the diseased area particularly when considering the possibility that the false lumen is dilated.

[0008] Therefore, the present invention has made with the above drawbacks in mind, it is a main object of the invention to provide a medical guide wire which is capable of inserting a front distal portion normally into a true lumen without being led astray, thereby contributing to treating and curing a diseased area quickly with high precision.

[0009] WO-A-9634635 discloses a medical guide wire according to the precharacterizing portion of claim 1.

[0010] According to the present invention, there is provided a medical guide wire comprising a flexible line wire having a main wire portion, a core line member and a helical spring provided around a distal end of said core line member, a front end of said helical spring being fixedly interfit to a head plug provided at a tip of said core line member;

wherein a rigid portion is located on a front end of said helical spring, and a loosely wound portion as an elastically expandable portion is defined from a rear end of said head plug,

wherein a clearance between line element turns of said loosely wound portion is in a range of 10% to 30% of the line diameter of said helical spring,

characterized in that:

the length extending lengthwise from a top end of said head plug to a rear end of a portion in which said helical spring is fixed to said head plug, which includes said rigid portion, measures 0.5mm or less; and

in that an intermediary location is determined on an intermediary portion of said helical spring in which an intermediary boss portion is secured to said core line member to define said loosely wound portion from the rear end of said head plug to said intermediary location; and

in that said loosely wound portion is at least 20 mm in length.

[0011] In the medical guide wire of the invention the length of the rigid portion is exceedingly reduced at a distal end of a helical spring. An elastically expandable portion extends rearward from the rigid portion to increase a flexibility of a front distal portion of the helical spring. The structure is such that the front distal portion of the medical wire is improved at its flexibility to enhance an operable feeling transmitted from the front distal portion of the helical spring upon advancing the front distal portion into a blood vessel.

[0012] In order to reduce the length of the rigid portion of the helical spring, the helical spring is preferably secured to a head plug by means of a TIG welding, laser spot welding or the like. The rigid portion extends lengthwisely from a top of the head plug to a rear end of a portion in which the helical spring is secured to the head plug. The length of the rigid portion measures 0.5 mm or less (preferably by 0.2 mm or less).

[0013] A loosely wound portion extends as an elastically expandable portion from the rigid portion. The elastically expandable portion measures at least 20 mm in length, such as approximately 24 mm or more in length, so as to exceed an entire length of the generally predictable diseased area. A width of a clearance appeared between line element turns of the loosely wound portion is 10 % or more of a line diameter of the helical spring. A function panel-test based on a sample piece shows that a feeling of the handling knob abruptly deteriorates when the clearance reduces to less than 10% of the line diameter of the helical spring. This is a reason why 10 % of the line diameter of the helical spring is defined as a lower limit of the clearance.

[0014] With a technical concept in mind that the head plug advances smoothly into the diseased area of the nonuniform vascular tract in combination with a manipulation of the medical guide wire, the head plug forms a spherical or semi-spherical configuration, and right and left side portions of the head plug are in part undercut to form flat surface portions in order to reduce a resistance that the head plug receives when advancing along the vascular tract, thereby improving a directional maneuverability of the head plug. In order to further improve the directional maneuverability of the head plug, a core line member is rectangular in cross section, longer sides of which position in parallel with the flat surface portion of the head plug.

[0015] According to the medical guide wire thus structured, the length of the front rigid portion is reduced and the loosely wound portion extended as rearward from the rigid portion is elastically expandable at its line element turns when an outer force is applied to the loosely wound portion. The front distal portion has an elastically workable section which enhances a contact-adaptability and contact-detectability against the diseased area so as to remarkably ameliorate an operable feeling of the handling knob of the medical guide wire.

[0016] When the front distal portion is inserted into the blood vessel to be pushed, pulled and turned, the loosely wound portion meets the diseased area to elastically expand and contract the line element turns due to a contact resistance against the diseased area while admitting a soft lesion tissue of the diseased area between the line element turns of the loosely wound portion. Due to a relativity between the soft lesion tissue of the diseased area and the line element turns which adimits the soft lesion tissue, an apparent change of feeling can be perceived on the handling knob to enhance a feeling precision transmitted from the loosely wound portion.

[0017] According further to the medical guide wire in which the length of the rigid portion is reduced, the front distal portion enhances a preshape capability to readily bend into a doglegged-shaped configuration substantially free from an accident in which the front distal portion is unexpectedly broken, while improving a traceability of advancing the front distal portion along a bifurcated and turned blood vessel. Other actions and effects of the present invention will be expounded in embodiments followed.

[0018] Embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Fig. 1 is a side elevational view of a medical guide wire according to a first embodiment of the invention;
Fig. 2 is a longitudinal cross sectional view of a main part of the medical guide wire;
Fig. 3 is an explanatory view showing the medical guide wire when it is inserted into a blood vessel;
Fig. 4 is another explanatory view showing the medical guide wire when it is inserted into the blood vessel;
Fig. 5 is a longitudinal cross sectional view of a front distal portion inserted into a diseased area of the blood vessel;
Fig. 6 is another longitudinal cross sectional view of the front distal portion inserted into the diseased area of the blood vessel;
Fig. 7 is an explanatory view showing the medical guide wire when it is inserted into the blood vessel;
Fig. 8 is another explanatory view showing the medical guide wire when it is inserted into the blood vessel;
Figs. 9~11 are sequential views showing how to manufacture the front distal portion of the medical guide wire;
Fig. 12 is a longitudinal cross sectional view of a head plug according to a second embodiment of the invention;
Fig. 13 is a plan view of the head plug of Fig. 12;
Fig. 14 is a longitudinal cross sectional view of a head plug according to a third embodiment of the invention;
Fig. 15 is a side elevational view of a prior art medical guide wire but partially sectioned; and
Fig. 16 is an explanatory view showing the prior art medical guide wire when it is inserted into a blood

vessel.

[0019] Referring to Figs. 1 through 8 which show a medical guide wire 1 (referred to merely as "guide wire" hereinafter) according to a first embodiment of the present invention, a core line 3 is formed by thinning a distal end of a main wire portion 2 of a flexible line wire as shown in Figs. 1 and 2. To a distal end of the core line 3, a spherical or semi-spherical head plug 5 is secured which has a stem portion 5a extended in one piece

[0020] When the front distal portion 10 passes through the intima 21 and advances into the media 22 which is formed by the smooth muscle and the elastic fibers, a sticky resistance is uniquely felt when the front distal portion 10 is pulled. The sticky resistance is positively transmitted to the manipulator so that the manipulator advances the front distal portion 10 into an abnormal position. Namely, by pushing and pulling the front distal portion 10 with the loosely wound portion 8 advanced into the media 22, the loosely wound portion 8 admits the collagen fiber tissue 24 into the clearance C to change the degree of resistance against collagen fiber tissue 24 as understood from Fig. 5 and 6. Therefore, the guide wire 1 is effective in assisting to introduce the front distal portion 10 into the obstruction area P as well as to prevent the front distal portion 10 from being led astray into the false lumen.

[0021] The guide wire 1 is particularly effective in introducing the front distal portion 10 into a bifurcated and turned portion of the blood vessel 20. When the obstruction area P appears on the bifurcated and turned portion of the blood vessel 20, while the prior rigid portion is likely led astry into the false lumen as shown at broken lines in Figs. 7 and 8, the front distal portion 10, however, favorably follows along the bifurcated and turned portion of the blood vessel 20 due to its good pliability and the preshaped tip provided with the front distal portion 10.

[0022] The length L4 of the highly pliable front distal portion 10 is approximately 24 mm so that the front distal portion 10 is positively useful for the obstruction area P of maximum length (approx. 15 mm) which is commonly observed in the most general diseased area. Because the welding between the helical spring 4 and the head plug 5 is due to the TIG welding or laser spot welding procedure in a protective atmosphere, the normal function of the front distal portion 10 is maintained and preventing an entry of foreign matters to avoid the very thin wire from being broken caused by the reduced strength.

[0023] Figs. 9 ~ 11 shows a method how to manufacture the head plug 5. The tightly wound helical spring is firstly provided around the core line 3, and the head plug 5 is secured to the tip of the core line 3 extended beyond the helical spring 4 with the use of a ball-shaped soldering material (0.2 mm in dia.) and its surface tension appeared when the ball-shaped soldering material is molten.

[0024] In this instance, a discrete head plug may be secured to the tip of the core line 3 by means of caulking. As other alternative, the tip of the core line 3 may be plastically deformed to define the head plug 5.

[0025] The front portion of the helical spring is, in some degree, expanded to interfit its two or three turns to the stem portion 5a of the head plug 5, and the soldering, TIG welding or laser spot welding is applied to the portion in which the helical spring 4 is fixedly secured to the stem portion 5a with the dispersion of the filler metal or flux prevented during the welding operation.

[0026] Thereafter, the clearance C between the line element turns of the loosely wound portion 8 is determined, and the intermediary location 11 is soldered to the intermediary boss.portion 9 which is provided beforehand on the core line 3.

[0027] Upon welding the helical spring 4 and the head plug 5 to form the rigid portion 4A within 0.5 mm in length, the ball-shaped soldering material (0.2 mm in dia.) may be used instead of the TIG welding or laser spot welding. In this instance, the method includes forming the plug head 5 by welding the core line 3 and helical spring 4 with the soldering material, and by bulging the core line 3 by applying the laser spot welding or TIG welding to the core line 3 and helical spring 4.

[0028] Figs. 12 and 13 show a second embodiment of the invention in which right and left sides of the spherical portion of the head plug 5 are symmetrically undercut along a central line 14 to form flat portions 13 in a parallel direction. The flat portions 13 enable the head plug 5 to an enhanced directional maneuverability when the handling knob 7 is operated. In order to further enhance the directional maneuverability, the flat portions 13 are positioned out of the parallel but arranged such as to render the head plug 5 tapered off in the axial direction. Otherwise, it is preferable that the flat portions 13 are positioned in parallel with longer sides of the core line 3 which is formed rectangular in cross section.

[0029] Figs. 14 shows a third embodiment of the invention in which an outer surface of a head plug 5A is roughened instead of machining a mirror finish. The roughened surface of the head plug 5A enables the manipulator to feel an increase contact resistance against the obstruction area P so as to improve an operable feeling.

Claims

1. A medical guide wire (1) comprising a flexible line wire having a main wire portion (2), a core line member (3) and a helical spring (4) provided around a distal end of said core line member (3), a front end of said helical spring (4) being fixedly interfit to a head plug (5) provided at a tip of said core line member (3);
   wherein a rigid portion (4A) is located on a front end of said helical spring (4), and a loosely wound portion (8) as an elastically expandable portion is defined from a rear end of said head plug (5),
   wherein a clearance (C) between line element turns

of said loosely wound portion (8) is in a range of 10% to 30% of the line diameter of said helical spring (4), **characterized in that**:

the length (L3) extending lengthwise from a top end of said head plug (5) to a rear end of a portion in which said helical spring (4) is fixed to said head plug (5), which includes said rigid portion (4A), measures 0.5mm or less; and
in that an intermediary location (11) is determined on an intermediary portion of said helical spring (4) in which an intermediary boss portion (9) is secured to said core line member (3) to define said loosely wound portion (8) from the rear end of said head plug (5) to said intermediary location (11); and
in that said loosely wound portion (8) is at least 20 mm in length.

2. The medical guide wire (1) according to claim 1, wherein said head plug (5) forms a spherical or semispherical configuration, and a right and left side portion of said head plug (5) are undercut to form flat surface portions (13).

3. The medical guide wire (1) according to claim 1, wherein a right and left side portion of said head plug (5) are undercut to form flat surface portions (13).

4. The medical guide wire (1) according to claim 2 or 3, wherein said core line member (3) is rectangular in cross section, longer sides of which position in parallel with said flat surface portions (13) of said head plug (5).

5. The medical guide wire (1) according to any one of claims 1 to 4, wherein said loosely wound portion (8) is approximately 24 mm in length.

6. The medical guide wire (1) according to any of claims 1 to 5, wherein said front end of said helical spring (4) and said head plug (5) are joined by TIG welding or laser spot welding.

Patentansprüche

1. Medizinischer Führungsdraht (1), umfassend einen flexiblen Leitungsdraht mit einem Drahthauptabschnitt (2), einem Kernleitungselement (3) und einer spiralförmigen Feder (4), die um ein distales Ende des Kernleitungselements (3) herum gebracht ist, wobei ein vorderes Ende der spiralförmigen Feder (4) an einer Kopfendenkappe (5) fest angebracht ist, die an der Spitze des Kernleitungselements (3) aufgesetzt ist;
wobei ein starrer Abschnitt (4A) an einem vorderen Ende der spiralförmigen Feder (4) lokalisiert ist, und ein lose herumgewundener Abschnitt (8) als ein elastisch expandierbarer Abschnitt von der hinteren Seite der Kopfendenkappe (5) aus abgegrenzt ist,
wobei ein Abstand (C) zwischen den Leitungselement-Windungen des lose herumgewundenen Abschnitts (8) in einem Bereich von 10 % bis 30 % des Leitungsdurchmessers der spiralförmigen Feder (4) liegt,
dadurch gekennzeichnet, dass:

die Länge (L3), die sich der Länge nach von einem vorderen Ende der Kopfendenkappe (5) bis zu einem hinteren Ende eines Abschnitts, in welchem die spiralförmige Feder (4) an der Kopfendenkappe (5) fixiert ist, erstreckt, und die den starren Abschnitt (4A) enthält, 0,5 mm oder weniger misst; und
dass eine dazwischen liegende Stelle (11) auf einen dazwischen liegenden Abschnitt der spiralförmigen Feder (4) festgelegt ist, wobei ein dazwischen liegender Muffenabschnitt (9) an dem Kernleitungslement (3) befestigt ist, um den lose herumgewundenen Abschnitt (8) von dem hinteren Ende der Kopfendenkappe (5) zu der dazwischen liegenden Stelle (11) abzugrenzen; und
dass der lose herumgewundene Abschnitt (8) mindestens 20 mm lang ist.

2. Medizinischer Führungsdraht (1) nach Anspruch 1, wobei die Kopfendenkappe (5) eine kugelförmige oder halbkugelförmige Gestalt bildet, und ein rechter und linker Seitenabschnitt der Kopfendenkappe (5) unterschnitten sind, um flache Oberflächenabschnitte (13) zu bilden.

3. Medizinischer Führungsdraht (1) nach Anspruch 1, wobei ein rechter und linker Seitenabschnitt der Kopfendenkappe (5) unterschnitten sind, um flache Oberflächenabschnitte (13) zu bilden.

4. Medizinischer Führungsdraht (1) nach Anspruch 2 oder 3, wobei das Kernleitungselement (3) von rechteckigem Querschnitt ist, dessen längere Seiten in paralleler Position zu den flachen Oberflächenabschnitten (13) der Kopfendenkappe (5) sind.

5. Medizinischer Führungsdraht (1) nach einem der Ansprüche 1 bis 4, wobei der lose herumgewundene Abschnitt (8) etwa 24 mm lang ist.

6. Medizinischer Führungsdraht (1) nach einem der Ansprüche 1 bis 5, wobei das vordere Ende der spiralförmigen Feder (4) und die Kopfendenkappe (5) durch WIG-Schweißen oder Laserstrahlschweißen verbunden sind.

Revendications

1. Fil de guidage médical (1) comprenant un fil de ligne souple ayant une partie principale (2) de fil, un élément de ligne central (3) et un ressort hélicoïdal (4) disposé autour d'une extrémité distale dudit élément de ligne central (3), une extrémité avant dudit ressort hélicoïdal (4) étant assujettie à un embout de tête (5) disposé à un bout dudit élément de ligne central (3) ;
dans lequel une partie rigide (4A) est située à une extrémité avant dudit ressort hélicoïdal (4), et une partie (8) à enroulement lâche constitue une partie pouvant se déployer par élasticité est définie à partir d'une extrémité arrière dudit embout de tête (5),
un jeu (C) entre des spires d'élément de ligne de ladite partie (8) à enroulement lâche étant dans la plage de 10% à 30% du diamètre de ligne dudit ressort hélicoïdal (4),
caractérisé en ce que :

la longueur (L3) s'étendant longitudinalement depuis une extrémité supérieure dudit embout de tête (5) jusqu'à une extrémité arrière d'une partie dans laquelle ledit ressort hélicoïdal (4) est fixé audit embout de tête (5), qui comporte ladite partie rigide (4A), mesure 0,5 mm ou moins ;
un emplacement intermédiaire (11) est déterminé sur une partie intermédiaire dudit ressort hélicoïdal (4), dans laquelle un bossage intermédiaire (9) est fixé audit élément de ligne central (3) afin de définir ladite partie (8) à enroulement lâche depuis l'extrémité arrière dudit embout de tête (5) jusqu'audit emplacement intermédiaire (11) ; et
ladite partie (8) à enroulement lâche a une longueur d'au moins 20 mm.

2. Fil de guidage médical (1) selon la revendication 1, dans lequel ledit embout de tête (5) présente une configuration sphérique ou hémisphérique, et les parties latérales droite et gauche dudit embout de tête (5) sont creusées pour former des parties à surface plane (13).

3. Fil de guidage médical (1) selon la revendication 1, dans lequel des parties latérales droite et gauche dudit embout de tête (5) sont creusées pour former des parties à surface plane (13).

4. Fil de guidage médical (1) selon la revendication 2 ou 3, dans lequel ledit élément de ligne central (3) a une section transversale rectangulaire, dont les grands côtés sont placés parallèlement auxdites parties à surface plane (13) dudit embout de tête (5).

5. Fil de guidage médical (1) selon l'une quelconque des revendications 1 à 4, dans lequel ladite partie à enroulement lâche (8) a une longueur d'environ 24 mm.

6. Fil de guidage médical (1) selon l'une quelconque des revendications 1 à 5, dans lequel ladite extrémité avant dudit ressort hélicoïdal (4) et ledit embout de tête (5) sont assemblés par soudage TIG ou par soudage laser par points.

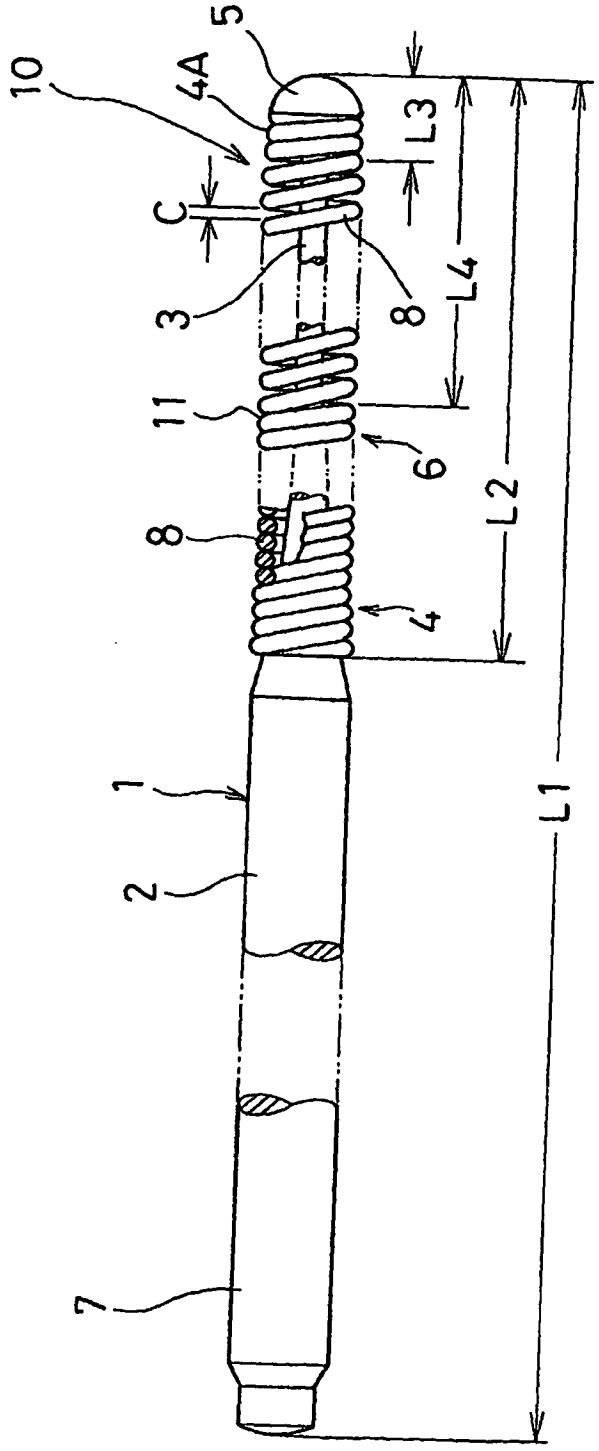


Fig.1

Fig.2

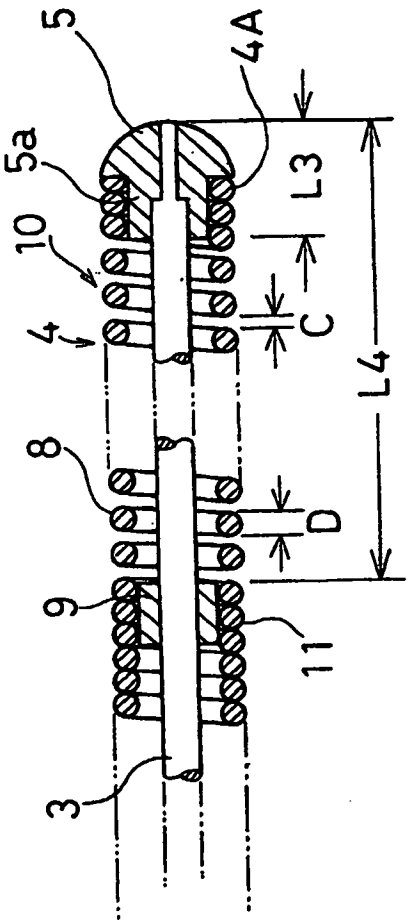


Fig.3

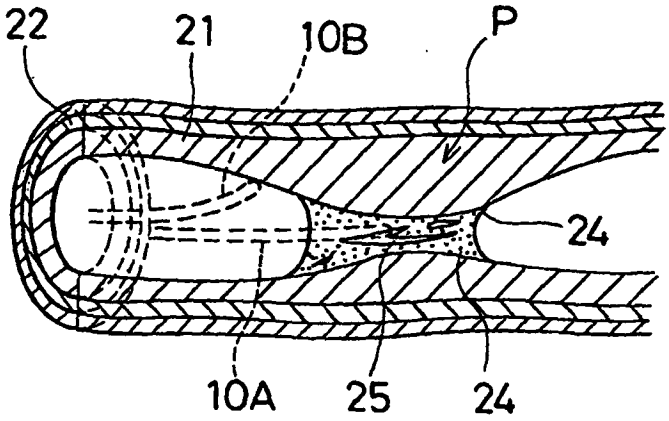


Fig.4

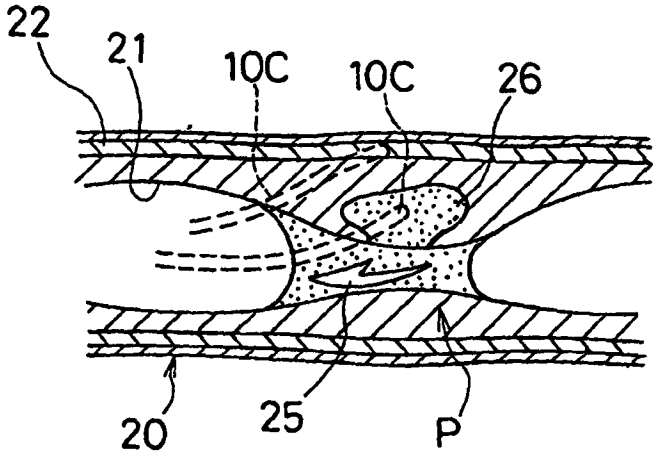


Fig.5

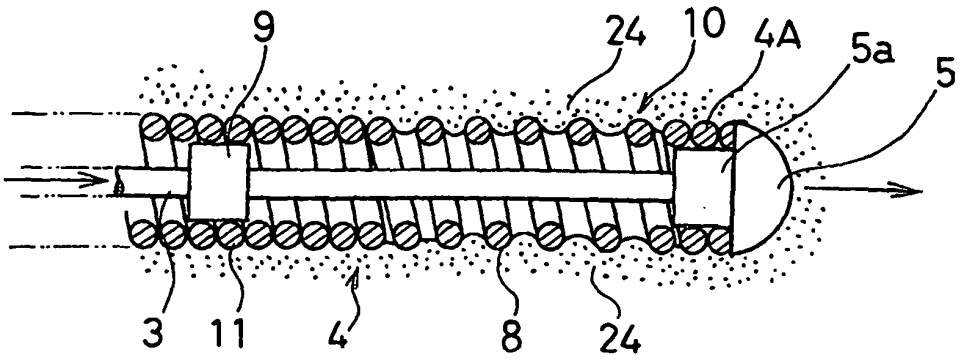


Fig.6

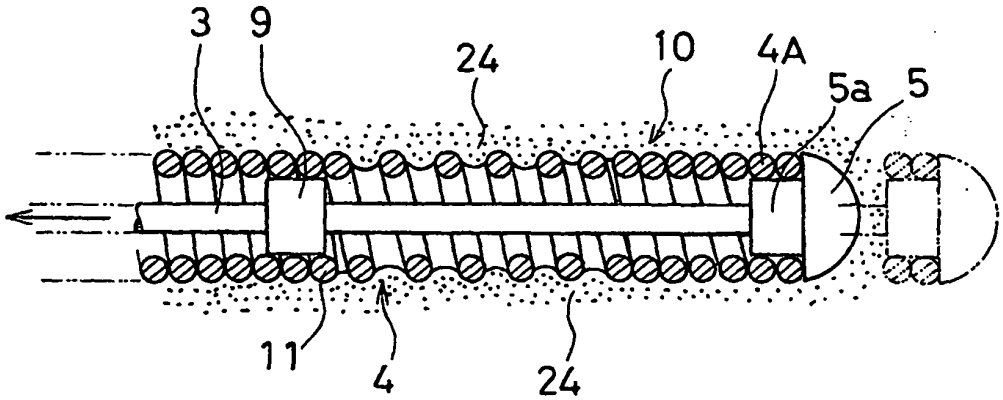


Fig.7

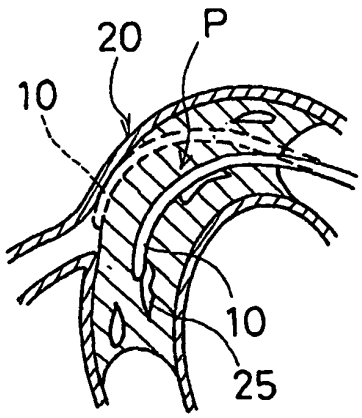


Fig.8

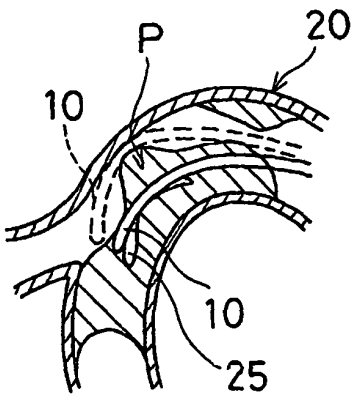


Fig.9

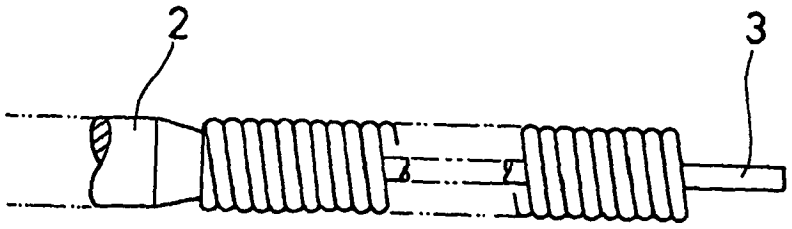


Fig.10

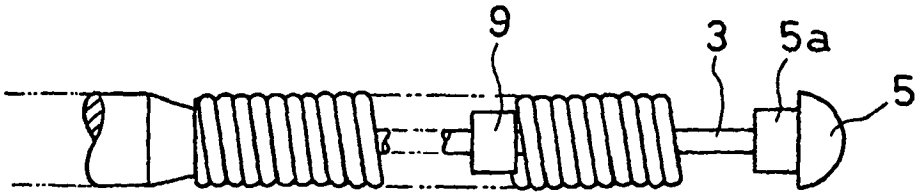


Fig.11

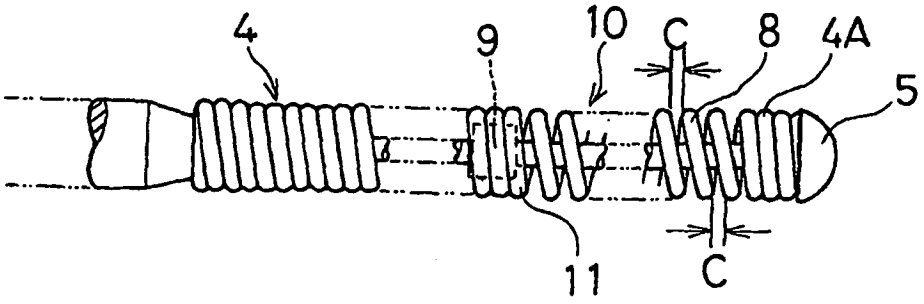


Fig.12

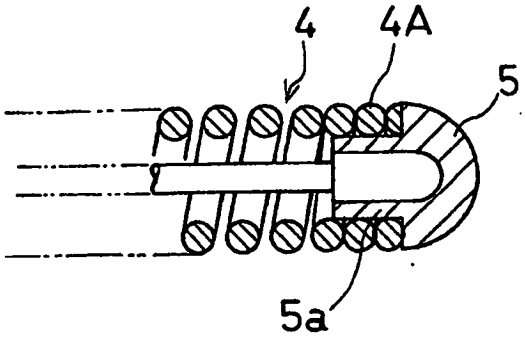


Fig.13

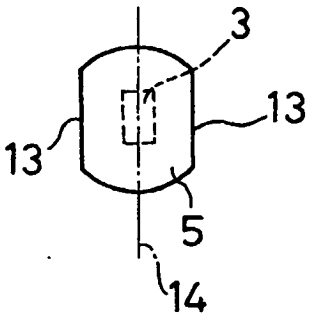


Fig.14

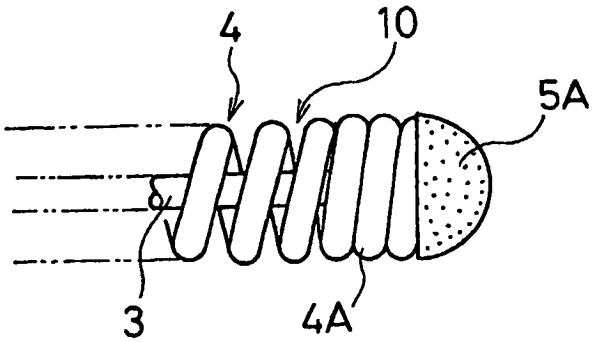


Fig.15

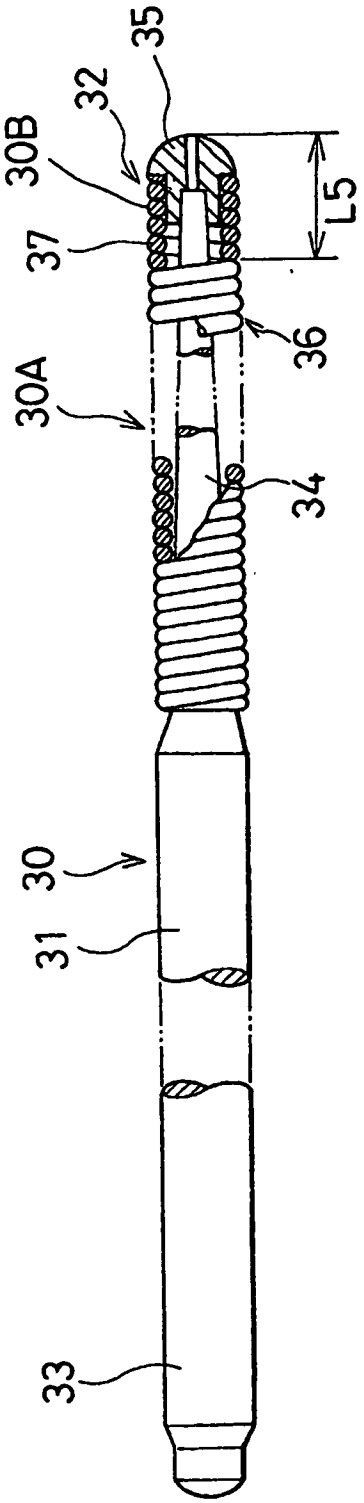
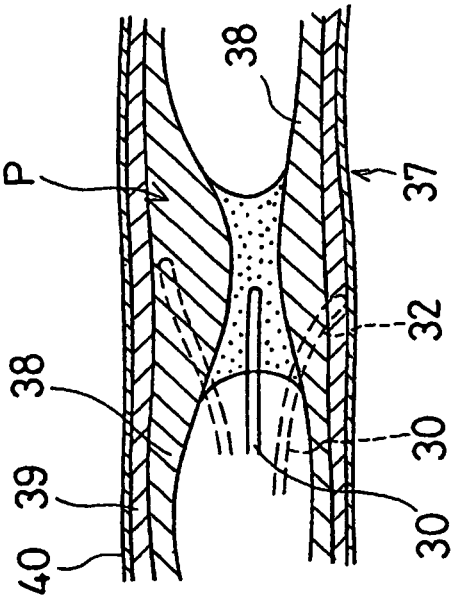


Fig.16



REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- JP 4025024 A **[0002]**
- JP 3060674 A **[0003]**
- WO 9634635 A **[0009]**

专利名称(译)	医用导丝		
公开(公告)号	EP1321162B1	公开(公告)日	2008-01-23
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外部链接	Espacenet		

摘要(译)

在医疗导丝（1）中，刚性部分（4A）位于螺旋弹簧（4）的远端，并且刚性部分（4A）的尺寸为0.5mm或更小，其从头部的顶端延伸插头（5）到螺旋弹簧（4）固定在头插头（5）上的部分的后端，中间位置（11）固定在芯线的中间凸起部分（9）上（3）由于松散卷绕部分的线元件匝之间的间隙（C），从头部插头（5）的后端到中间位置（11）提供松散卷绕部分（8），以便可弹性扩张（8）。

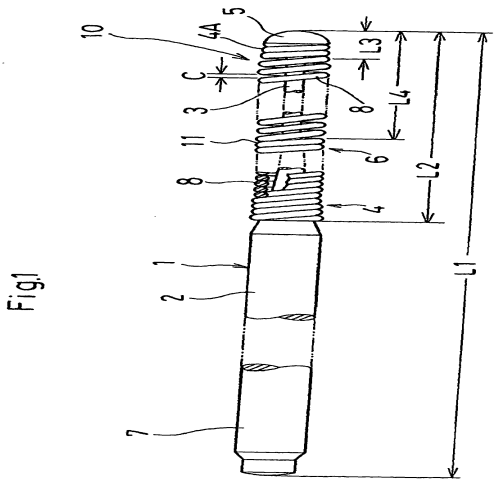

Fig.1