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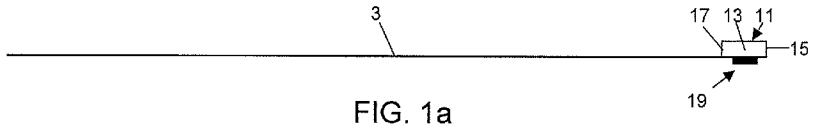

FIG. 1a

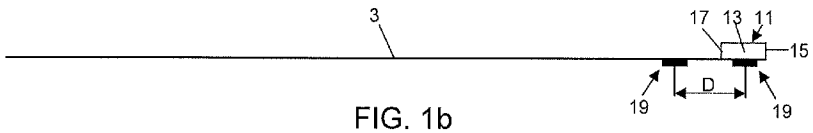

FIG. 1b

(57) Abstract: Rapid exchange guide unit comprising an elongated support member 3, and a guide wire member (11) provided with a guide wire lumen (13) having a distal guide wire opening (15) and a proximal guide wire opening (17), the guide wire lumen is arranged close to the distal end of said elongated support member, and is adapted to receive a guide wire. The rapid exchange guide unit further comprises at least one sensor (19) arranged close to the distal end of the elongated support member, and being adapted to measure a parameter in a living body, and to generate a sensor signal in dependence of the measured parameter. The sensor signal is applied to a signal processing unit adapted to process the sensor signal and to generate a processed sensor signal.

WO 2011/034491 A1

Title

Rapid exchange guide unit

Field of the invention

The present invention relates to a rapid exchange guide unit according to the preamble of the independent claim.

Generally, a so called rapid exchange catheter includes features that allows for easy exchange of the guide unit without the removal of the guide wire.

This invention relates to a rapid exchange guide unit with multiple utilities for use inside mammalian tubular vessels or structures, and more particularly allows the guide unit to be removed from around a guide wire by using a slot or channel to hold the guide wire.

Background of the invention

During catheter-based procedures, the physician often visualizes the area being treated under fluoroscopy and visualizes the catheter and/or treatment area using radio-opaque materials. Contrast dyes are used to visualize the treated area by injecting a contrast dye through the catheter while the fluoroscope is being operated. The physician can then see the vessel in which the catheter is positioned, as well as any lesion past which the contrast dye flows.

In the procedure, the physician may use a guiding device, such as a guide wire, to controllably reach the lesion or area to be treated. Once the guide wire is in position, the physician may need to pass one or more catheters, tubular devices, and/or medical devices along the guide wire to the lesion or treatment area. The physician may pull the catheter or tubular device back along the guide wire and finally off of the guide wire. A difficulty of this, however, is that the guide wire must be very long (i.e. longer than the catheter) in order to pull the catheter off the guide wire without needing to first also pull the guide wire out of the patient. A known solution to this problem is the use of a rapid exchange configuration in which the distal end of the catheter has a pair of openings into a lumen and through which the guide wire may be passed by inserting the proximal end of the guide wire through the distal most opening and then passing the proximal end of the guide wire out of the proximal opening of the lumen. For example, such a configuration is described in U-5,451,233.

Also WO/2003/039626 relates to a rapid exchange catheter with stent deployment, therapeutic infusion, and lesion sampling features.

One common application of rapid exchange and marker catheters is during coronary angioplasty, which refers to the use of an inflatable balloon to increase the blood flow through a stenosis (i.e. a partially blocked section of a blood vessel feeding the heart). A typical coronary angioplasty consists of three steps. First, a physician inserts a guiding catheter into a patient's blood vessel, typically through the femoral artery at the top of the patient's leg. The guiding catheter is advanced toward the heart through the patient's blood vessel, stopping short of the coronary arteries, and is then fixed in place. Next, the physician inserts a guide wire into the guiding catheter until the distal end of the guide wire exits the guiding catheter and enters the coronary artery. The physician then positions the guide wire across the stenosis to be treated in the coronary artery, and the guide wire is fixed in place.

Finally, the physician advances a balloon catheter along the guide wire until the balloon exits the guiding catheter and is positioned across the stenosis. The physician then inflates the balloon to treat the stenosis, deflates the balloon, and removes the balloon catheter without disturbing the placement of either the guide wire or the guiding catheter.

Physicians frequently need to exchange balloon catheters during a single coronary angioplasty procedure. For example, if a stenosis blocks most of the blood flow through a vessel, the physician may first need to use a small balloon to increase the size of the opening through the stenosis, and then use a larger balloon to further increase the opening. Another example of a catheter exchange is when a physician uses a first balloon catheter to open a lumen and a second catheter to deploy a stent.

Catheters are used in a variety of minimally invasive medical procedures. A major portion of the catheter field involves catheters that track over a guide wire, such as angioplasty catheters that are used to advance an inflatable member over a guide wire to a desired vascular location. One advancement in this field has been the use of rapid exchange catheters in place of standard over-the-wire catheters.

A standard over-the-wire catheter typically tracks over a guide wire over its entire length such that, in order to maintain a distal guide wire location while exchanging the catheter, a guide wire extension or very long guide wire is used. To exchange the standard over-the-wire catheter, the guide wire is held in place while the catheter is withdrawn. The proximal end of the guide wire is held until the distal end of the catheter exits the patient's body, while the distal end of the guide wire remains in the desired location, meaning that the guide wire, during exchange, must be twice as long as the catheter.

A rapid exchange catheter tracks over the guide wire for only a short distal portion of the catheter. Examples of rapid exchange catheters, their use, and methods for making such catheters are illustrated by US-6,409,863. The catheter shown by the US-patent includes an outer member and a distally located inner member, with a balloon proximal end attached to the distal end of the outer member and a balloon distal end attached to the distal inner member. A proximal guide wire port is located distal of the proximal end of the catheter, with the distal inner member opening at its proximal end to the proximal guide wire port, and extending to the distal end of the catheter.

According to the general procedure when determining vessel constrictions first a conventional guide wire is inserted and guided into e.g. a coronary vessel to be investigated. Then a catheter, preferably a so called rapid exchange catheter, is threaded over the guide wire and inserted and guided by the guide wire into the measurement site in the coronary vessel. Contrast fluid is then inserted, via the catheter, into the measurement site in the vessel. By viewing the site using angiography, the physician visually determines the significance of the constriction, and whether e.g. a stent placement or ballon expansion needs to be performed.

An alternative to using visual determination of the significance of a constriction is using measurement of fractional flow reserve (FFR). FFR is defined as the ratio of distal (to stenosis) pressure (Pd) to aortic pressure (Pa) during hyperemia. US-6,565,514, assigned to the same assignee as the present application, discloses a method and system for determining physiological variables such as arterial blood pressure. For determining the so

called Myocordial Fractional Flow Reserve, FFR_{myo}, two pressures must be measured, namely the arterial pressure before a stenosis, and the pressure distally of the stensosis. FFR_{myo} is defined as maximum myocordial flow in the presence of a stenosis in the supplying epicardial coronary artery, divided by normal maximum flow. FFR_{myo} is calculated by means of the formula:

$FFR_{myo} = (P_d - P_v)/(P_a - P_v) = P_d / P_a$, wherein

- P_d =arterial pressure at maximum hyperemia;
- P_a =distal coronary pressure at maximum hyperemia;
- P_v =central venous pressure at maximum hyperemia.

It is a lesion-specific index of the functional severity of the stenosis and can be obtained by intracoronary pressure measurement by a guide wire-mounted pressure sensor. During PTCA, balloon angioplasty or Percutaneaus Transluminal Coronary Angioplasty, the separate contributions of coronary and collateral blood flow to maximum myocardial perfusion can be obtained.

Thus, an object of the device of US-6,565,514, is to provide improved systems for monitoring physiological variables, in particular for pressure measurements in the coronary vessels, and especially for the reliable determination of Fractional Flow Reserve, FFR_{myo}.

Thus, if a constriction should be further investigated it is sometimes necessary to measure the pressure and flow in the vessel. The Fractional Flow Reserve (FFR) value may then be determined which gives a clear indication of the constriction, and in order to calculate the FFR the pressure values distally and proximally the constriction are required.

In the procedure used today, the guide wire is then either replaced by a guide wire provided with a pressure sensor at the distal end and the pressure measurements are then performed, or a guide wire provided with a pressure sensor at its distal end is inserted via another lumen of the catheter into the site of interest. This is often regarded as a rather

lengthy and complicated procedure and the object of the present invention is to improve the procedure and the devices used today.

More generally, the object of the present invention is to provide an improved rapid exhange procedure which also facilitates measurements of physiological variables and other variables inside the vessel.

Summary of the invention

The above-mentioned object is achieved by the present invention according to the independent claim.

Preferred embodiments are set forth in the dependent claims.

According to the present invention a sensor is arranged at the distal end of the rapid exchange guide unit. The sensor is adapted to measure a parameter in a living body, and to generate a sensor signal in dependence of the measured parameter. The sensor signal is applied to a signal processing unit adapted to process the sensor signal and to generate a processed sensor signal. The guide wire member has further a longitudinal extension of 1-5 cm, and the inner diameter of the guide wire lumen is less than 2 mm.

According to one preferred embodiment, the sensor is a pressure sensor, which pressure sensor comprises a sensor support body (a "sensor chip") provided with a diaphragm covering a cavity formed in the support body having a pressure sensitive element mounted on the diaphragm, for recording pressure. The pressure sensitive element is preferably a piezoresistive element. A pressure sensor applicable in connection with the present invention is disclosed in US-6,615,667, assigned to the assignee in the present application. This known sensor has an exemplary geometrical extension of 0,18 mm x 1,3 mm x 0,18 mm.

According to another embodiment of the present invention the guide unit comprises an elongated guide member being in the form of a catheter, essentially being a hollow tube, and is provided with a sensor at its distal end adapted to perform measurements. Thereby

the measurements may be performed directly and as a consequence no additional measurement guide wire has to be inserted. In addition the measurements are performed at exactly the correct position in that no positioning is required as it is when inserting a dedicated guide wire.

Furthermore, the measurements may be performed essentially at the same time as the fluid contrast is inserted and expelled from the distal opening of the catheter, thereby saving time.

According to the present invention an improved rapid exchange guide unit is achieved that enables more accurate, less expensive measurement procedures to be performed, that in addition facilitates the physician to perform the angioplasty, i.e. restoration of normal blood flow, by laser surgery or balloon expansion, at an even higher grade of accuracy with regard to position of the constriction.

Short description of the appended drawings

Figure 1a shows a schematic side view of the rapid exchange guide unit according to the present invention.

Figure 1b shows a schematic side view of the rapid exchange guide unit provided with two sensors according to an embodiment of the present invention.

Figure 2a shows a schematic side view of the rapid exchange guide unit according to a first embodiment.

Figure 2b shows a schematic side view of the rapid exchange guide unit provided with two sensors according to a first embodiment.

Figure 3a shows a schematic side view of the rapid exchange guide unit according to a second embodiment.

Figure 3b shows a schematic side view of the rapid exchange guide unit provided with two sensors according to a second embodiment.

Figure 4 shows a schematic block diagram illustrating the functional parts of the present invention.

Figures 5-8 show schematic side views of the catheter wall illustrating different arrangements of a pressure sensor in the wall.

Detailed description of preferred embodiments of the invention

The present invention will now be described in detail with references to the appended drawings. The drawings illustrate the schematic structure of different embodiments, and are not in a correct scale, e.g. with regard to the size of the sensor in relation to the elongated guide member.

Figure 1a shows a schematic side view of the rapid exchange guide unit according to the present invention. The rapid exchange guide unit comprises an elongated support member 3 and a guide wire member 11 provided with a guide wire lumen 13 having a distal guide wire opening 15, and a proximal guide wire opening 17, the guide wire lumen is arranged close to the distal end of said elongated support member, and is adapted to receive a guide wire. The distance between the proximal guide wire opening 17 and the distal end of the elongated support member 3 is in the range of 1-5 cm.

The rapid exchange guide unit further comprises at least one sensor 19 arranged close to the distal end of the elongated support member, and being adapted to measure a parameter in a living body, and to generate a sensor signal in dependence of the measured parameter. The generated sensor signal is applied to a signal processing unit (see figure 4) adapted to process the sensor signal and to generate a processed sensor signal. The measured parameter may be a physiological variable, e.g. pressure, temperature, or flow, or a physical variable, e.g. electromagnetic waves or radio waves. Thus, according to one embodiment the sensor is used to sense physical parameters, e.g. electromagnetic waves or radio waves. This embodiment is applicable in situations when the position of the sensor is to be determined. One or many radio wave signals is then generated from outside the body and from different directions and the position of the sensor may then be determined by analysing reflected signals. The sensor is e.g. a frequency tuned circuit.

The elongated support member may be in the form of a wire, or in the form of a thin metal tubing. The support member may also be in the form of a combination of a wire and a metal tubing. The elongated support member, according to this embodiment, has the

advantage of having a thin structure along the major part of its length, it is only at its distal end where the guide wire lumen is arranged that the width is slightly increased.

The guide unit further comprises a connector unit arranged at the proximal end of the catheter for attachment to an external device. The connector unit provides for electrical connection to the signal processing unit and to the sensor.

In an alternative embodiment the signal processing unit is instead arranged in a proximal part of the guide unit or at an external device to which the guide unit is attached. According to this alternative embodiment the raw unprocessed sensor signal is supplied by the electrical cable(s) along the guide member to the signal processing unit.

In one embodiment the signal processing unit comprises a Wheatstone bridge, or any equivalent circuitry adapted to filter, amplify and process the measured sensor signal.

According to an alternative embodiment the processed sensor signal, or the unprocessed sensor signal, may be wirelessly transferred to an external device, e.g. an external monitor (not shown).

According to one preferred embodiment of the present invention, the sensor is adapted to measure pressure. The pressure sensor then comprises a sensor support body with a maximal geometrical extension of 1,5 mm and is provided with a diaphragm covering a cavity formed in the support body having a pressure sensitive element mounted on the diaphragm, for recording pressure. According to this preferred embodiment, the pressure sensitive element is a piezoresistive, piezocapacitive or a piezoelectric element.

However, as an obvious constructional variation, the sensor may instead or in combination with measuring pressure, be adapted to measure one or many of temperature, flow, and position.

In Figure 1b, another preferred embodiment of the present invention is shown, wherein two sensors 19 are arranged at a predetermined distance D from each other in the

longitudinal direction of the elongated guide member 3. The predetermined distance D may be such that, when in use, the proximal sensor senses a reference parameter in relation to the parameter sensed by the distal sensor. The predetermined distance D is approximately 5 - 20 mm. The distance D between the two sensors is preferably chosen such that when one sensor is arranged proximally a suspected stenosis, the other sensor will then be arranged distally the stenosis.

In a further embodiment of the present invention, the guide unit comprises an elongated guide member being in the form of a guide wire or catheter, provided with a sensor comprising a magnetic detection probe, for detecting a plurality of magnetic fields, and being part of a medical positioning system, such as that described in US 6,233,476 and US 2004/0097804.

With reference to figures 2a and 3a, showing schematic side views of the rapid exchange guide unit according to a second and a third embodiment of the invention will now be described in detail. In the lower part in each of the figures 2a and 3a a cross-sectional view along A-A is shown.

In the rapid exchange guide unit 2, 2' according to the second and third embodiments the elongated guide member 3 is a catheter member 4, 4' provided with a catheter lumen 6, 6' having a proximal catheter opening 8, 8' and a distal catheter opening 10, 10', preferably arranged to expel contrast fluid at a measurement site, and a guide wire member 12, 12' provided with a guide wire lumen 14, 14' having a distal guide wire opening 16 and a proximal guide wire opening 18, 18'. The guide wire lumen runs essentially parallel to the catheter lumen and is adapted to receive a guide wire.

Furthermore, the proximal guide wire opening is arranged at a location along the catheter member distally of the proximal catheter opening of the catheter member, and that the distal guide wire opening is arranged at a location close to the distal catheter opening.

The catheter further comprises at least one sensor 20, 20' arranged close to the distal end of the catheter. The sensor is adapted to measure a parameter in a living body, and to

generate a sensor signal in dependence of the measured parameter. The sensor signal is applied to a signal processing unit (see figure 4), preferably arranged in connection with the sensor adapted to process the sensor signal and to generate a processed sensor signal (see figure 4). The catheter further comprises a connector unit arranged at the proximal end of the catheter for attachment to an external device. The connector unit provides for electrical connection, and also a fluid tight connection when e.g. a contrast fluid is to be supplied to the catheter.

In an alternative embodiment the signal processing unit is instead arranged in a proximal part of the catheter or at an external device to which the catheter is attached. According to this alternative embodiment the raw unprocessed sensor signal is supplied by the electrical cable(s) along the catheter to the signal processing unit.

According to a preferred embodiment of the present invention, the sensor is a pressure sensor. The pressure sensor comprises a sensor support body with a maximal geometrical extension of 1,5 mm and is provided with a diaphragm covering a cavity formed in the support body having a pressure sensitive element mounted on the diaphragm, for recording pressure. The pressure sensitive element is a piezoelectric, piezoresistive or piezocapacitive pressure element.

However, as an obvious constructional variation, the sensor may instead or in combination with measuring pressure, be adapted to measure one or many of temperature, flow, and position.

In one embodiment the signal processing unit comprises a Wheatstone bridge, or any equivalent circuitry adapted to filter, amplify and process the measured sensor signal.

According to an alternative embodiment the processed sensor signal, or the unprocessed sensor signal, may be wirelessly transferred to an external device, e.g. an external monitor (not shown).

In figures 2b and 3b further embodiments of the present invention are shown, wherein two sensors are arranged a predetermined distance D from each other in the longitudinal direction of the catheter. The predetermined distance D may be such that, when in use, the proximal sensor senses a reference parameter in relation to the parameter sensed by the distal sensor.

According to a preferred embodiment, the sensors are sensitive to pressure. The predetermined distance may then be such that, when in use, the proximal pressure sensor senses a reference pressure in relation to the pressure sensed by the distal pressure sensor, and the obtained pressure values may be used to determine Fractional Flow Reserve (FRR) values.

With reference to figure 2a and 2b another embodiment of the present invention is illustrated where the guide wire member 12 is arranged such the guide wire lumen 14 runs parallel to and within the catheter lumen 6. The proximal guide wire member opening 18 is arranged as an opening in the catheter member wall.

With reference to figure 3a and 3b one embodiment of the present invention is illustrated where the guide wire member 12' is arranged such the guide wire lumen 14' runs parallel to and outside the catheter lumen 6'.

In the disclosed embodiments the guide wire member 12, 12' has an essentially tubular extension having a circular cross-section, naturally other geometrical shapes are possible, e.g. elliptical, elongated etc.

Furthermore, the guide wire member is here disclosed as a closed tube but also a tube provided with a longitudinal slot, e.g. at the upper part of the guide wire member 12' in figure 3, would be possible, through which slot a guide wire is pressed into the guide wire lumen. In that case the guide wire member must have a structural shape integrity to regain its original shape but have enough flexibility to allow the slot to be widened.

For all embodiments the guide wire member has a longitudinal extension in the order of 1-5 cm.

Preferably, the inner diameter of the guide wire lumen is less than the inner diameter of the catheter lumen. However, for the embodiment illustrated in figure 3a and 3b the diameters of the catheter lumen 6' and guide wire lumen 14' may be equal or the guide wire lumen may even have the larger diameter.

The inner diameter of the guide wire lumen is less than 3 mm, preferably less than 2 mm.

Preferably, the proximal catheter opening 8 is provided with a contrast fluid connection port that in turn is connectable, by use of the connector unit, to an external device (not shown in the figures) adapted to apply contrast fluid to the catheter.

Figures 5-8 show schematic side views of the catheter wall illustrating different arrangements of the pressure sensor in the catheter wall of the catheter member or guide wire member. These different arrangements are applicable to any of the above described embodiments illustrated in figures 1-3.

According to one embodiment the at least one pressure sensor is arranged at an outer surface of the catheter member or guide wire member, this is illustrated by figure 5.

According to another embodiment the at least one pressure sensor is arranged in a recess in the outer surface of the catheter member or guide wire member, this is illustrated by figure 6.

According to another embodiment the at least one pressure sensor is arranged at an inner surface of the catheter member or guide wire member, this is illustrated by figure 7. In figure 7 the sensitive part of the sensor is facing the arrow indicating pressure to be sensed. It is also possible to turn around the sensor such that the sensitive part instead faces the inner of the catheter member or guide wire member.

According to another embodiment the at least one pressure sensor is arranged in a catheter member wall or guide wire member, this is illustrated by figure 8. In this embodiment the catheter wall preferably is laminated whereas a recess is arranged in one of the layers adapted to receive the pressure sensor.

As illustrated in figures 5-8 the catheter further comprises one or many electrical cables connected to the at least one pressure sensor and said signal processing unit and running along the catheter, the cables being embedded in the catheter wall and connected to a connector unit arranged at the proximal end of the catheter.

The arrangements shown in figures 5-8 are also applicable to other types of sensor, such as sensors adapted to measure one or many of temperature, flow, and position.

In a further embodiment, not illustrated in the figures, the guide wire or catheter of the present invention comprises three sensors, each sensor measuring one or many of temperature, flow, and position. In one such embodiment, two sensors can determine pressure, while the third determines position.

The present invention is not limited to the above-described preferred embodiments. Various alternatives, modifications and equivalents may be used. Therefore, the above embodiments should not be taken as limiting the scope of the invention, which is defined by the appending claims.

Claims

1. Rapid exchange guide unit comprising an elongated support member (3,4,4') and a guide wire member (11,12,12') provided with a guide wire lumen (13,14,14') having a distal guide wire opening (15,16,16') and a proximal guide wire opening (17,18,18'), the guide wire lumen is arranged close to the distal end of said elongated support member, and is adapted to receive a guide wire, said guide wire member has a longitudinal extension of 1-5 cm, and that the inner diameter of the guide wire lumen is less than 2 mm, c h a r a c t e r i z e d i n that the rapid exchange guide unit further comprises at least one sensor (19,20,20') arranged close to the distal end of the elongated support member, and being adapted to measure a parameter in a living body, and to generate a sensor signal in dependence of the measured parameter, wherein said sensor signal is applied to a signal processing unit adapted to process the sensor signal and to generate a processed sensor signal.

2. Rapid exchange guide unit according to claim 1, wherein said sensor (19, 20, 20') is a pressure sensor (19, 20, 20'), which comprises a sensor support body with a maximal geometrical extension of 1,5 mm provided with a diaphragm covering a cavity formed in the support body having a pressure sensitive element mounted on the diaphragm, for recording pressure, said pressure sensitive element being a piezoresistive, piezocapacitive or a piezoelectric element, wherein said pressure signal is applied to said signal processing unit adapted to process the pressure signal and to generate a processed pressure signal.

3. Rapid exchange guide unit according to any of claims 1-2, wherein said elongated support member (3) being in the form of a wire.

4. Rapid exchange guide unit according to any of claims 1-2, wherein said elongated support member (3) being in the form of a thin metal tubing.

5. Rapid exchange guide unit according to any of claims 1-2, wherein said elongated support member (3) being in the form of a combination of a wire and a metal tubing.

6. Rapid exchange guide unit according to any of claims 1-2, wherein said elongated support member being a catheter member (4, 4') provided with a catheter lumen (6, 6') having a proximal catheter opening (8, 8') and a distal catheter opening (10, 10'), and that said guide wire lumen runs essentially parallel to the catheter lumen, wherein the proximal guide wire opening is arranged at a location along the catheter member distally of the proximal catheter opening of the catheter member, and that the distal guide wire opening is arranged at a location close to the distal catheter opening.

7. Rapid exchange guide unit according to claim 6, wherein said at least one sensor is arranged at an outer surface of the catheter member.

8. Rapid exchange guide unit according to claim 6, wherein said at least one sensor is arranged in a recess in the outer surface of the catheter member.

9. Rapid exchange guide unit according to claim 6, wherein said at least one sensor is arranged at an inner surface of the catheter member.

10. Rapid exchange guide unit according to claim 6, wherein said at least one sensor is arranged in a catheter member wall.

11. Rapid exchange guide unit according to any of claims 1-6, wherein said at least one sensor is arranged at an outer surface of the guide wire member.

12. Rapid exchange guide unit according to any of claims 1-6, wherein said at least one sensor is arranged in a recess in an outer surface of the guide wire member.

13. Rapid exchange guide unit according to any of claims 1-6, wherein said at least one sensor is arranged at an inner surface of the guide wire member.

14. Rapid exchange guide unit according to any of claims 1-6, wherein said at least one sensor is arranged in a guide wire member wall.

15. Rapid exchange guide unit according to any preceding claim, wherein two sensors are arranged a predetermined distance from each other in the longitudinal direction of the guide unit.

16. Rapid exchange guide unit according to claim 15, wherein said predetermined distance is such that, when in use, the proximal sensor senses a reference parameter in relation to the parameter sensed by the distal sensor.

17. Rapid exchange guide unit according to claim 16, wherein said sensors are pressure sensors, each sensing a pressure value, and that said obtained pressure values are used to determine Fractional Flow Reserve (FRR) values.

18. Rapid exchange guide unit according to any of claims 1-2, wherein the guide unit further comprises electrical cables connected to said at least one sensor and said signal processing unit and running along the unit and connected to a connector unit arranged at the proximal end of the guide unit.

19. Rapid exchange guide unit according to claim 6, wherein the guide wire member is arranged such the guide wire lumen runs parallel to and outside said catheter lumen.

20. Rapid exchange guide unit according to claim 6, wherein the guide wire member is arranged such the guide wire lumen runs parallel to and within said catheter lumen.

21. Rapid exchange guide unit according to claim 20, wherein the proximal guide wire member opening is arranged as an opening in the catheter member wall.

22. Rapid exchange guide unit according to claim 6, wherein the inner diameter of the guide wire lumen is less than the inner diameter of the catheter lumen.

23. Rapid exchange guide unit according to any of claims 1-2, wherein the inner diameter of the guide wire lumen is less than 1 mm.

24. Rapid exchange guide unit according to any of claims 1-2, wherein said processed sensor signal is wirelessly transferred to an external monitor.

25. Rapid exchange guide unit according to any of claims 1-24, wherein said measured parameter is a physiological variable or other physical variable.

26. Rapid exchange guide unit according to claim 25, wherein said sensor is adapted to measure one or many of temperature, flow, and position.

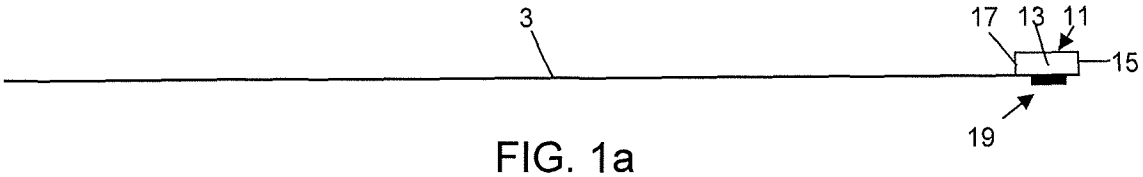

FIG. 1a

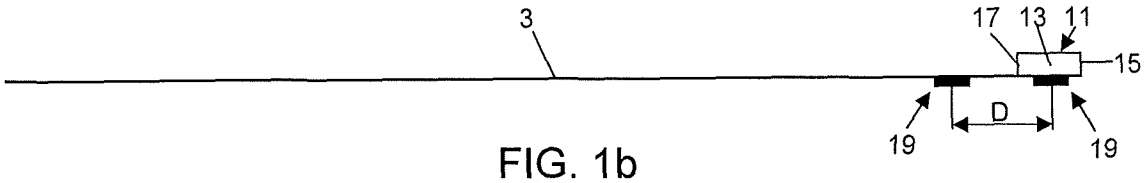

FIG. 1b

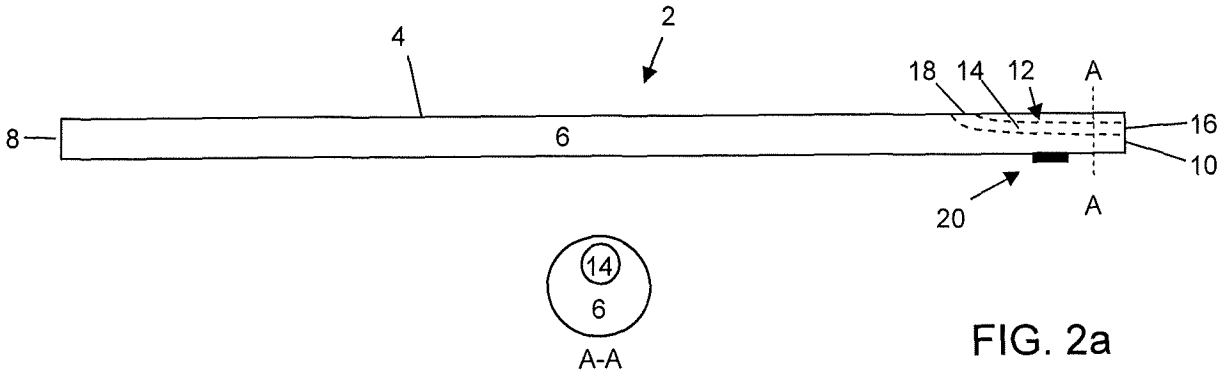

FIG. 2a

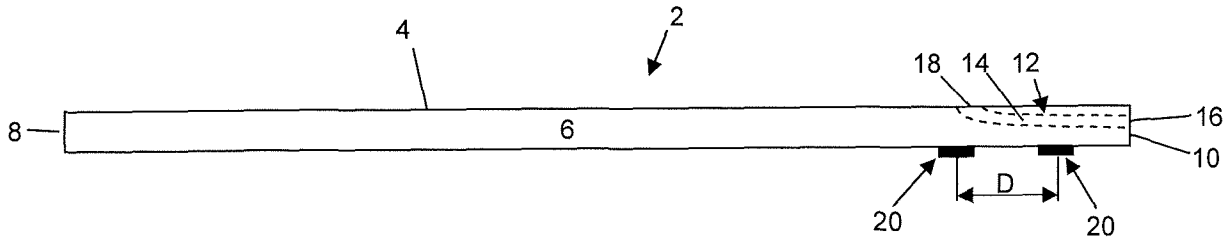

FIG. 2b

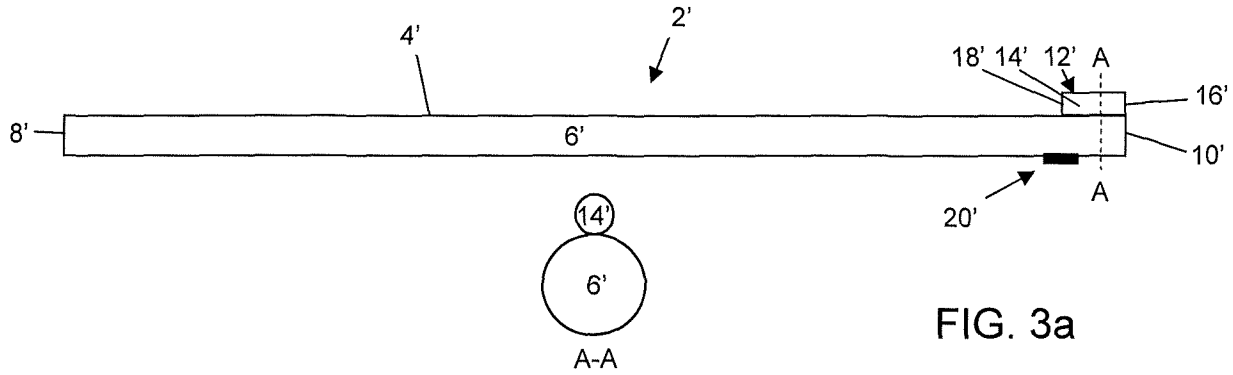

FIG. 3a

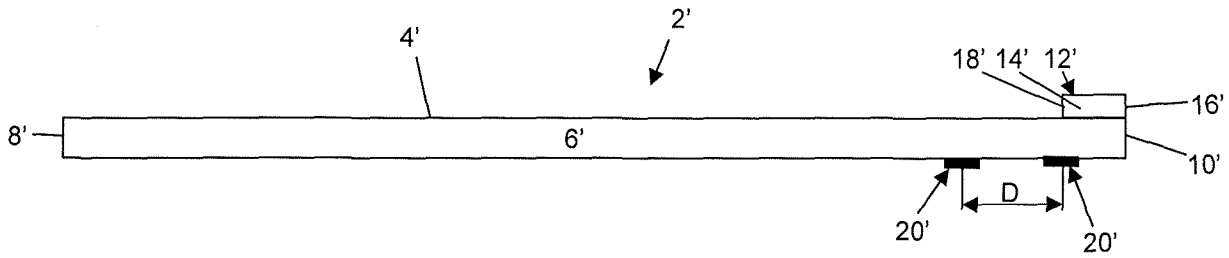

FIG. 3b

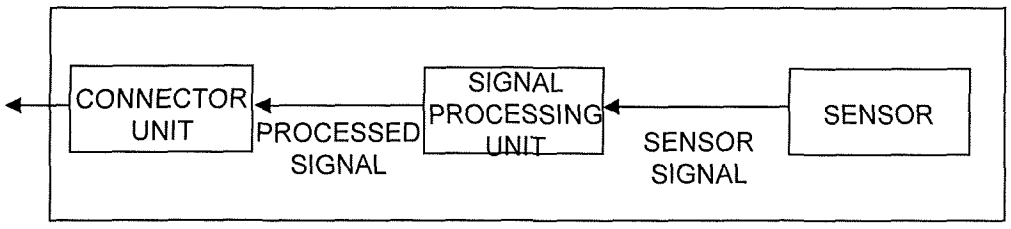

FIG. 4

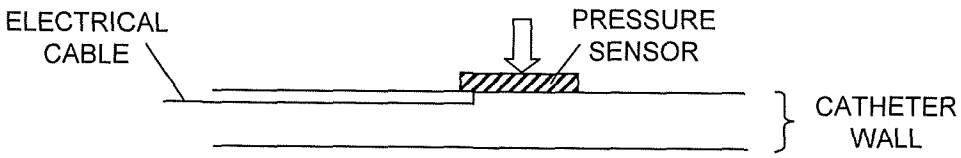

FIG. 5

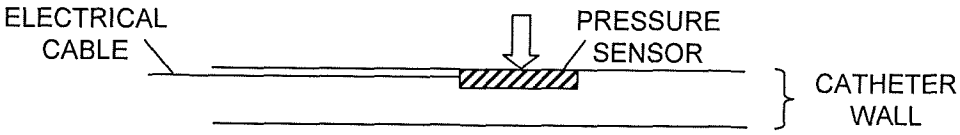

FIG. 6

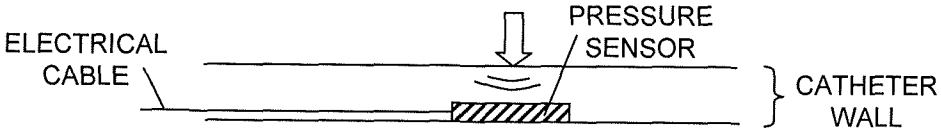

FIG. 7

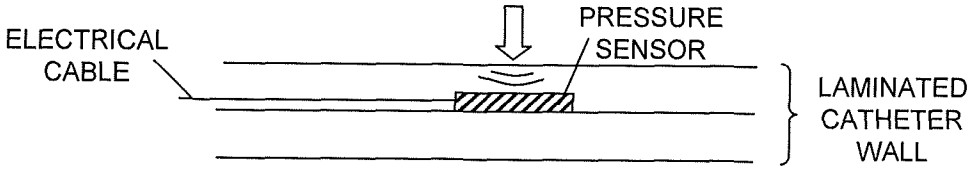

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2010/050988

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet
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: A61M, A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 20090177275 A1 (CASE), 9 July 2009 (09.07.2009), figures 1,8, abstract, paragraphs (0030), (0034)-(0035),(0039)-(0041)	1,3-14,18-26
Y	--	2,15-17
X	US 20080208252 A1 (MAKOWER), 6 Sept 2007 (06.09.2007), abstract, paragraphs (0076),(0096)	1,3-14,18-26
Y	--	2,15-17
Y	US 6343514 B1 (SMITH), 5 February 2002 (05.02.2002), column 2, line 32 - line 64, abstract	2
	--	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
14 October 2010	28 -10- 2010
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Sara Backman / JA A Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6471656 B1 (SHALMAN ET AL), 29 October 2002 (29.10.2002), figure 8, abstract	15-17
	--	
A	WO 9610434 A1 (MEDTRONIC, INC.), 11 April 1996 (11.04.1996), figures 1,9A-9E, abstract	1-26
	--	
A	US 5873835 A (HASTINGS ET AL), 23 February 1999 (23.02.1999), column 1, line 36 - line 55; column 10, line 60 - line 64; column 12, line 17 - line 24, column 14, lines 6-19; abstract	1-26
	--	
A	US 20050124939 A1 (KONSTANTINO), 9 June 2005 (09.06.2005), abstract, paragraphs (0007)-(0010), (0034)	1-26
	--	
A	US 20030163052 A1 (MOTT ET AL), 28 August 2003 (28.08.2003), figures 1-2, abstract, paragraphs (0002),(0101)	1-26
	--	
E	US 20100241008 A1 (BELLEVILLE ET AL), 23 Sept 2010 (23.09.2010), whole document	1-26
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International patent classification (IPC)

A61M 25/01 (2006.01)
A61B 5/0215 (2006.01)

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Cited literature, if any, will be enclosed in paper form.

US	20090177275	A1	09/07/2009	NONE			
US	20080208252	A1	06/09/2007	NONE			
US	6343514	B1	05/02/2002	DE	69725703	D,T	17/06/2004
				EP	0877574	A,B	22/10/2003
				SE	0877574	T3	
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WO	9610434	A1	11/04/1996	AU	3762495	A	26/04/1996
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US	20050124939	A1	09/06/2005	NONE			
US	20030163052	A1	28/08/2003	NONE			
US	20100241008	A1	23/09/2010	NONE			

专利名称(译)	快速交换引导装置		
公开(公告)号	EP2477685A1	公开(公告)日	2012-07-25
申请号	EP2010817517	申请日	2010-09-14
[标]申请(专利权)人(译)	ST犹达医疗SYST		
申请(专利权)人(译)	ST.犹达医疗系统公司		
当前申请(专利权)人(译)	ST.犹达医疗协调中心BVBA		
[标]发明人	SMITH LEIF		
发明人	SMITH, LEIF		
IPC分类号	A61M25/01 A61B5/0215 A61B5/00		
CPC分类号	A61B5/0215 A61B5/02158 A61B5/6852 A61M2025/0002 A61M2025/0183		
优先权	61/242502 2009-09-15 US 0950671 2009-09-15 SE		
其他公开文献	EP2477685A4		
外部链接	Espacenet		

摘要(译)

快速交换引导单元，包括细长支撑构件3，以及引导线构件（11），引导线构件（11）设置有引导线腔（13），引导线腔（13）具有远端引导线开口（15）和近端引导线开口（17），引导线内腔靠近所述细长支撑构件的远端布置，并且适于接收导丝。快速交换引导单元还包括至少一个传感器（19），其布置在细长支撑构件的远端附近，并且适于测量活体中的参数，并且根据测量的参数产生传感器信号。 。传感器信号被施加到信号处理单元，该信号处理单元适于处理传感器信号并产生处理后的传感器信号。