PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 5/00 — A1

(11) International Publication Number: **WO 99/26682**

(43) International Publication Date: 3 June 1999 (03.06.99)

(21) International Application Number: PCT/US98/19908

(22) International Filing Date: 23 September 1998 (23.09.98)

(30) Priority Data:
1007148 26 September 1997 (26.09.97) NL

(71) Applicant *(for all designated States except US)*: CORDIS CORPORATION [US/US]; 14201 N.W. 60th Avenue, Miami Lakes, FL 33014 (US).

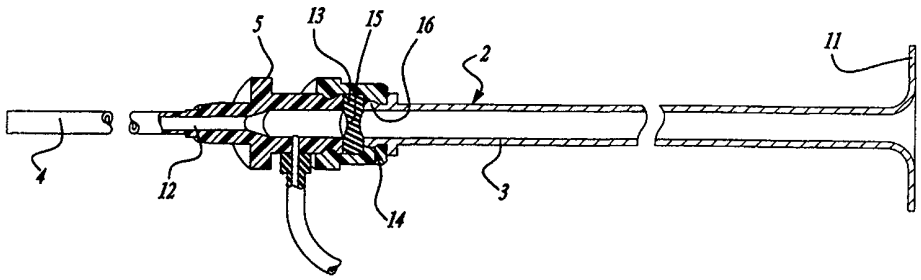
(71)(72) Applicants and Inventors: HURTAK, Wenzel, Franz [NL/NL]; Aan De Vaart 10, NL–9301 TZ Roden (NL). MOUS, Frans [NL/NL]; Ploeggang 6, NL–9203 HP Drachten (NL). NAP, Cornelis, Philipus [NL/NL]; Oude Streek 10, NL–9345 AG Zevenhuizen (NL).

(74) Agent: MONTGOMERY, Michael, W.; 14201 N.W. 60th Avenue, Miami Lakes, FL 33014 (US).

(81) Designated States: AU, CA, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: INTRAVASCULAR CATHETER SYSTEM WITH CONVERTIBLE SHEATH EXTENSION FOR MAGNETIC RESONANCE IMAGING AND METHOD



(57) Abstract

This invention relates to an intravascular catheter system that includes a catheter introduction sheath (1), as well as a convertible sheath extension (3) for use during magnetic resonance procedures. The catheter introduction sheath (1) includes a tubular basic body (4) with a hemostatic valve (13) at its proximal end, is adapted to allow the selective insertion or various intravascular devices, such as catheters and guidewires. The catheter sheath introducer (1) is inserted percutaneously within the vascular system of a patient. The hemostatic valve (13) resists leaking of blood, while automatically opening and closing to allow vascular devices of differing types to be inserted and removed. In addition, the convertible sheath extension (3) has an elongated tubular body (2) with a proximal flange or handle (11), and also has a selectively detachable coupling (14) adapted to cooperate with the valve housing (5) of the catheter sheath introducer (11).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

INTRAVASCULAR CATHETER SYSTEM WITH CONVERTIBLE SHEATH EXTENSION FOR MAGNETIC RESONANCE IMAGING AND METHOD

BACKGROUND AND SUMMARY OF THE INVENTION

1. Technical Background:

The present invention relates generally to intravascular medical devices, and more particularly to an intravascular catheter system.

2. Discussion:

The invention relates to a catheter introduction sheath. Such a catheter introduction sheath is arranged percutaneously in a blood vessel of a patient after which a guidewire, catheter etc. may be introduced through the introduction sheath into the vascular system of the patient. The usual catheter introduction sheath has been provided at its proximal end with a hemostatic valve in order to prevent loss of blood and through which the guidewire and catheter etc. are inserted.

With certain types of treatment, the site where a catheter introduction sheath has been introduced into the patient can not be reached or only with great difficulty, for instance when the patient has been received in the tunnel or room of a magnetic resonance imaging device. This device may surround the patient so closely that access to the introduction sheath is no longer possible. In order to introduce or change the guidewire or the catheters in that case, the patient will have to be pulled out of the magnetic resonance imaging device, so that the person carrying out the procedure can gain access to the introduction sheath. By pulling the patient repeatedly

from the device and repositioning him inside it again, the treatment will last too long, which is uncomfortable to the patient and is in addition very expensive.

A good example of a catheter sheath introducer is described in the commonly assigned United States Patent number 4,874,378, issued to Hillstead on October 17, 1989, which is incorporated in this disclosure by reference.

As the body of the patient is of course opaque, physicians commonly use fluoroscopy or X-ray video cameras to track the position of intravascular devices within the body of a patient. In contrast to fluoroscopy, another method of visualizing the patient is magnetic resonance imaging, referred to as MRI. Other medical fields, such as neurology, often use procedures which are performed under magnetic resonance imaging instead of X-ray fluoroscopy.

The present invention provides an intravascular catheter system that includes a catheter introduction sheath, as well as a convertible sheath extension for use during magnetic resonance procedures. The catheter introduction sheath includes a tubular basic body with a hemostatic valve at its proximal end, and is adapted to allow the selective insertion of various intravascular devices, such as catheters and guidewires. The catheter sheath introducer is inserted percutaneously within the vascular system of a patient. The hemostatic valve resists leaking of blood, while automatically opening and closing to allow vascular devices of differing types to be inserted and removed. In addition, the convertible sheath extension has a selectively detachable coupling adapted to cooperate with the valve housing of the catheter sheath introducer. The convertible sheath extension thus extends the length of the catheter sheath introducer without interfering with the hemostatic valve, and can be coupled and removed from the catheter sheath introducer as desired. However, the convertible sheath extension does not increase the chance of blood coagulating in the system, since its lumen is

bloodless due to the intermediate location of the hemostatic valve. In addition, the convertible sheath extension may be transparent, to allow an operator to see vascular devices inserted therein. The convertible sheath extension may have various preselected flexibilities.

As the hemostatic valve has been arranged directly behind the insertion section, the guiding section will remain free of blood, as a result of which the risk of thrombi due to blood clots will be avoided in this section of the introduction sheath. The insertion section with the hemostatic valve connected to it may be introduced into the patient without the guiding section. Due to the absent extra length of the guiding section, the insertion section can be manipulated properly and carefully.

After positioning the insertion section together with the hemostatic valve, the guiding section may be arranged, after which the treatment may be carried out.

Preferably the basic body is made in such a way that it is stiffly flexible, which means that it has a considerably greater bending stiffness than a catheter or a guidewire, but is not entirely stiff.

In another embodiment, the element inserted into the guiding section of the introduction sheath is clearly visible. Accordingly, it can be established properly when the distal end of this element has reached the hemostatic valve, and that resistance experienced on further introduction is caused by this valve.

These and various other objects, advantages and features of the invention will become apparent from the following description and claims, when considered in conjunction with the appended drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of an intravascular catheter system for use with magnetic resonance imaging, arranged according to the present invention; and

Figure 2 is a partial longitudinal cross-section view of an intravascular catheter system for use with magnetic resonance imaging, arranged according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The following description of the preferred embodiments of the present invention is merely illustrative in nature, and as such it does not limit in any way the present invention, its application, or uses. Numerous modifications may be made by those skilled in the art without departing from the true spirit and scope of the invention.

The introduction sheath 1 illustrated in Figure 1 includes a tubular basic body 2. The tubular basic body is in the example of this embodiment assembled from a guiding section 3, an insertion section 4 and arranged in between, a valve housing 5 comprising a hemostatic valve 13.

The insertion section 4 is introduced percutaneously into a blood vessel of a patient in a manner known as such. Via the lumen 12 of the basic body 2, for instance a catheter 9 may be introduced subsequently into the vascular system of the patient. The catheter with the connecting member 10 has only been given here by way of an example. Also for instance a guidewire, a guiding catheter etc. may be introduced into a patient in the usual manner via an introduction sheath.

After introducing the insertion section 4, the hemostatic valve housing 5 is usually situated close to the site where the insertion section 4 has been introduced through the skin of the patient. This may for instance be in the inguinal area of the patient.

In case a magnetic resonance imaging procedure is to be carried out, and the room of the magnetic resonance imaging device which is to be used is so narrow that the inguinal area of the patient can no longer be reached when he is positioned inside the imaging device, the required supply and removal of the guidewire and/or catheters can be effected nonetheless via the guiding section 3, as the guiding section 3 forms a means of distant control for the insertion section 4.

The chosen length of the guiding section 4 is such that under the specific circumstances the proximal 10 end section of this guiding section 3 remains properly accessible so that elements such as a catheter 9 may be introduced into the patient.

At the proximal end of the guiding section 3 a supporting edge 11 has been formed, which provides a good support for the fingers of the person carrying out the procedure and which can be used for instance in order to generate the required counter pressure when pushing the catheter 9 through the hemostatic valve 13.

With the embodiment illustrated here, the lumen 12 has been provided with a branch pipe inside the hemostatic valve housing 5, to which a tube 6 has been connected which carries a tap 7 at its proximal end. Via the connection 8 of the tap 7 a fluid may be supplied to the lumen 12 and from there into the blood stream of the patient.

With the embodiment shown, the guiding section of the basic body 2 has been connected with the hemostatic valve housing 5 by means of a snap connector 14. This snap connector 14 is formed by a groove 15 extending around the lumen 12 into which a bulge 16, arranged at the distal end of the guiding section 3, can engage. By exerting an axial pressure to the guiding section 3, the latter may be clicked into the hemostatic valve housing 5 or removed from it.

After removing the guiding section 3 in this manner the hemostatic valve 13 remains active so that no unwanted loss of blood will occur.

As has been mentioned above, the guiding section 3 has been made of a transparent plastic material, so that the progress of the element inserted, like the catheter 9, can be monitored properly and that it can be established for instance when the distal end of the catheter inserted has to be pushed through the hemostatic valve 13.

The flexibility of the basic body 2 of the catheter introduction sheath 1 may vary along its length. The insertion section 4 may for instance be relatively flexible in order to prevent trauma and the guiding section 3 relatively stiff so that it can be handled easily. The stiffness of both the guiding section 3 and the insertion section 4 may vary along their lengths, depending on the required properties.

Furthermore, the lumen 12 may have been provided with a lubricating layer, so that the elements to be inserted, such as the catheter 9, can be passed through the introduction sheath 1 experiencing little friction.

It should be understood that an unlimited number of configurations for the present invention can be realized. The foregoing discussion describes merely exemplary embodiments illustrating the principles of the present invention, the scope of which is recited in the following claims. Those skilled in the art will readily recognize from the description, claims, and drawings that numerous changes and modifications can be made without departing from the spirit and scope of the invention.

CLAIMS

What is claimed is:

1. An intravascular medical catheter system for use in intravascular medical procedures, comprising:

a catheter sheath introducer having proximal and distal ends including a tubular basic body, and a hemostatic valve disposed at the proximal end of the catheter sheath introducer, the hemostatic valve incorporating a first fitting;

a convertible sheath extension including a tubular shaft defining a lumen, and a second fitting disposed at a distal end of the convertible sheath extension; and

a detachable coupling formed by the first and second fittings, adapted to allow the catheter sheath introducer and the convertible sheath extension to be selectively coupled and decoupled;

whereby said hemostatic valve resists blood from escaping whether or not the convertible sheath extension is coupled, such that the lumen of the convertible sheath extension tends to remain free of blood.

2. A catheter introduction sheath comprising a tubular basic body with a distal insertion section and a proximal guiding section wherein in between the insertion section and the guiding section a hemostatic valve has been arranged and wherein the guiding section has been connected in a detachable manner to the remainder of the basic body.

3. The catheter introduction sheath as set forth in claim 2, wherein the basic body is stiffly flexible.

4. The catheter introduction sheath as set forth in claim 2, wherein at least the guiding section has been made of a transparent plastic material.

5. The catheter introduction sheath as claimed in claim 2, wherein the guiding section has been connected to the remainder of the basic body by means of a snap connector.

6. Catheter introduction sheath as claimed in claim 2, wherein the inside of the tubular basic body has been provided with a coating for reducing friction.

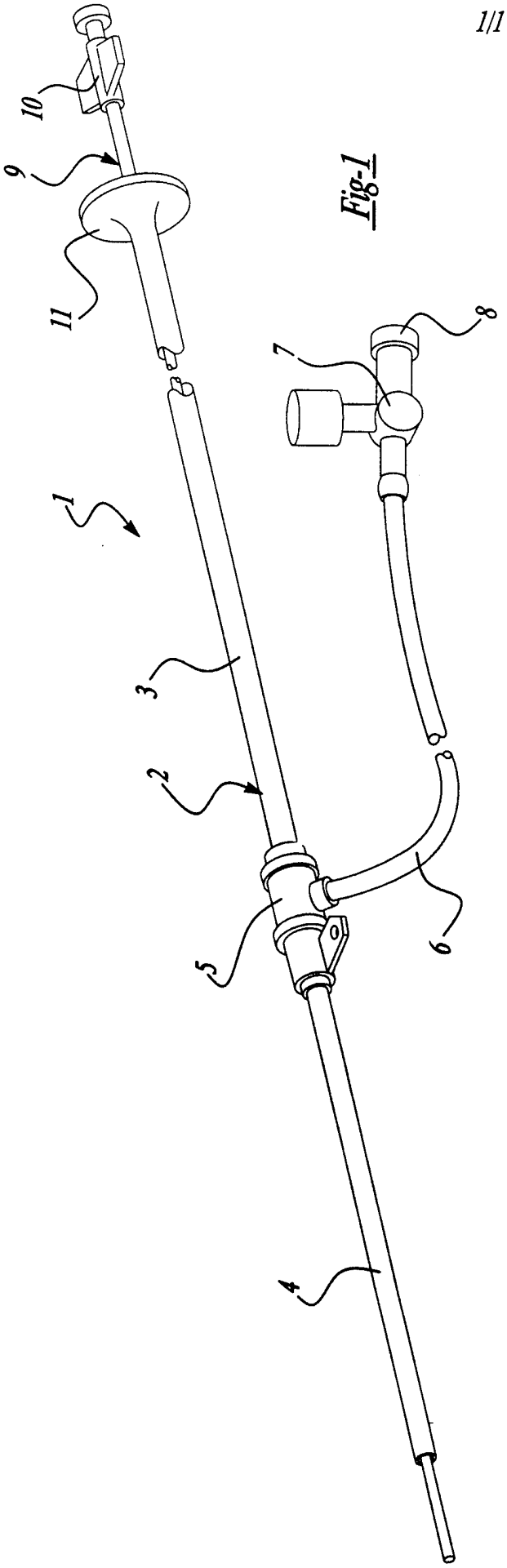


Fig-1

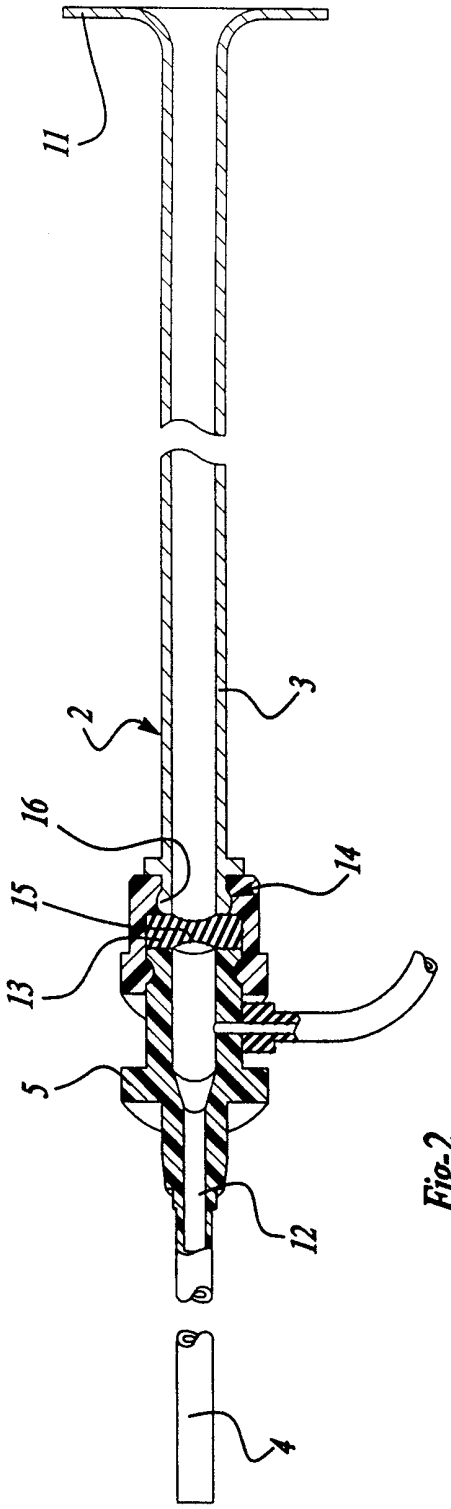


Fig-2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/19908

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61M 5/00
US CL :604/246
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/246, 171, 164, 169, 264, 256

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 practicable, search terms used)

GPIC terms: sheath introducer, sheath extension, coupling, valve

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,449,348 A (DRYDEN) 12 September 1995, specification.	1, 2, 4
X	US 4,834,710 A (FLECK) 30 May 1989, specification.	1-4

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

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search
19 JANUARY 1999

Date of mailing of the international search report
08FEB 1999

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703) 305-3230

Authorized officer
CRIS L. RODRIGUEZ
Telephone No. (703) 308-2194

Form PCT/ISA/210 (second sheet)(July 1992)★