

A U S T R A L I A
Patents Act 1990

NOTICE OF ENTITLEMENT

I ~~(We)~~ Frederick L. Schilling
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of 143 Eighth Street Del Mar CA 92014 United States of America

the applicant and nominated person in respect of an application for a patent for an invention
entitled Anchor pad for catheterization system

filed under Australian Application No. 20276/92, state the following:

PART 1 - Must be completed for all applications.

The person(s) nominated for the grant of the patent

is ~~(are)~~ the actual inventor(s)

or

has, for the following reasons, gained entitlement from the actual inventor(s)

PART 2 - Must be completed if the application is a Convention application.

The person(s) nominated for the grant of the patent is (are):

the applicant(s) of the basic application(s) listed on the patent request form

or

entitled to rely on the basic application(s) listed on the patent request form by reason of the following:

The basic application(s) listed on the request form is (are) the first application(s) made in a Convention country in respect of the invention.

PART 3 - Must be completed if the application was made under the PCT and claims priority.

The person(s) nominated for the grant of the patent is ~~(are)~~:

the applicant(s) of the application(s) listed in the declaration under Article 8 of the PCT

or

entitled to rely on the application(s) listed in the declaration under Article 8 of the PCT by reason of the following:

The basic application(s) listed in the declaration made under Article 8 of the PCT is ~~(are)~~ the first application(s) made in a Convention country in respect of the invention.

Dated this 2nd day of November 1993

Signed  Status Patent Attorney

Frederick L. Schilling

Signatory's Name

F.B. RICE & CO PATENT ATTORNEYS



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- (56) Prior Art Documents
US 4857058
WO 80/01458
US 4129128
- (57) Claim

1. An anchoring apparatus for securing a connector of a catheterization system to a body of a patient, wherein said catheterization connector comprises a substantially planar seat having holes formed therein of the type used for suturing, said anchoring apparatus characterized by:

an adhesive member for secure attachment to the body of the patient; and

at least one retention member mounted on said adhesive member and configured to insert through a corresponding hole of the connector seat and to engage with the connector seat about the hole to prevent accidental disengagement of the catheterization connector from said adhesive member, whereby the connector seat is attached to the adhesive member.

5. A method for anchoring a connector of a catheterization system to a body of a patient, wherein said .../2

(11) AU-B-20276/92

-2-

(10) 659174

catheterization connector includes a substantially planar seat having holes formed therein of the type used for suturing, said method characterized by the steps of:

providing an anchoring apparatus having an adhesive member and at least one retention member, said retention member extending outwardly away from said adhesive member;

placing said adhesive member on a patient body to secure said anchoring apparatus thereon with said retention member extending away from the patient body; and

inserting said retention member through said hole of said connector planar seat to prevent unintentional disengagement between the retention member and the planar seat of the catheterization connector.

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AOJP DATE 28/01/93 PCT NUMBER PCT/US92/03923

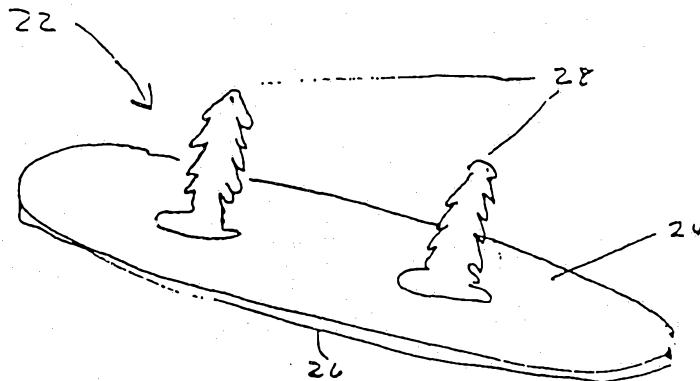


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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT).

<p>(51) International Patent Classification 5 : A61M 25/02</p>	<p>A1</p>	<p>(11) International Publication Number: WO 92/19309 (43) International Publication Date: 12 November 1992 (12.11.92)</p>
<p>(21) International Application Number: PCT/US92/03923 (22) International Filing Date: 7 May 1992 (07.05.92) (30) Priority data: 697,640 8 May 1991 (08.05.91) US (71)(72) Applicant and Inventor: BIERMAN, Steven, F. [US/US]; 143 Eighth Street, Del Mar, CA 92014 (US). (74) Agents: SHREVE, William, H. et al.; Knobbe, Martens, Olson and Bear, 620 Newport Center Drive, Suite 1600, Newport Beach, CA 92660 (US).</p>		<p>(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), SE (European patent).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p> <p>659174</p>

(54) Title: ANCHOR PAD FOR CATHETERIZATION SYSTEM



(57) Abstract

An anchor pad (22) is disclosed having a self-adhesive material applied to one surface (26) of the pad (22) and one or more barbed uprights (28) extending from the opposite surface (24) of the pad (22) in order to securely engage the suture holes (14) of a central line catheter (10). The barbs (28) permit slidable engagement with the catheter (10) but prevent disengagement. In order to remove the catheter (10), the barbs (28) can be easily snipped or cut.

ANCHOR PAD FOR CATHETERIZATION SYSTEM

Background of the Invention

Field of the Invention

5 The present invention relates to an anchor pad for an intravenous catheterization connector, and, more particularly, to an anchor pad for use with a triple-lumen connector.

Description of the Related Art

10 It is very common in the treatment of patients to utilize intravenous ("IV") catheters to introduce fluids and medications directly into the bloodstream. In many cases, and particularly with respect to cardiac therapy, the IV catheter is introduced into a central line or a larger vein located close to the patient's heart. In such circumstances, long term infusion typically requires that the catheter remain in
15 place for many days. In order to secure such a central line IV catheter in position at the injection site, the IV tubing is commonly mounted on a thin flexible pad or seat which is then sutured to the patient's skin. This combination of tubing and pad comprises a connector to which one or more
20 other IV supply lines having compatible connectors can be attached. In one example, a triple-lumen connector sold under the brand name ARROW® provides three separate supply lines for secondary IV fluids or manual injection sites.

25 A number of problems, however, have arisen with respect to such central line connectors such as the triple-lumen connector described above. First, suturing the pad to the patient's skin is painful. Also, with the passage of time, the sutures frequently tear through the soft plastic material comprising the seat of the connector, thus permitting movement
30 of the connector in the injection site and adding to the pain and discomfort of the patient. Even if they do not tear, the sutures may loosen to such an extent that 2 to 3 mm of movement occurs in and out of the injection site. This movement is not only painful to the patient, but also fosters
35 bacteria infections at the site. It is estimated that there are approximately 50,000 catheter infections per year in the United States, many of which are due to problems such as those described above.

SUBSTITUTE SHEET



Thus, there is a need for a more secure means for attachment of a central line catheter to the body of the patient at the injection site.

Summary of the Invention

5 The present invention comprises an anchor pad which securely fastens onto the body of the patient by means of an adhesive applied to one planar side of the pad. The opposite planar side of the pad includes one or more barbed uprights which engage the suture holes commonly found in typical
10 central line connectors, such as the triple-lumen connector described above. In the preferred embodiment, the barbed uprights correspond to the number, size and spacing of the connector suture holes.

 The triple-lumen connector mounts on the anchor pad of
15 the present invention by aligning the suture holes in the plastic seat of the connector over the barbed uprights on the anchor pad. The connector is then pressed down over the barbs until the connector is secure. The configuration of the barbs permits movement of the connector toward the body of the
20 patient but prevents movement in the opposite direction, thus preventing accidental disengagement.

 When it is necessary or desirable to remove the central line connector, the barbs can be easily and quickly snipped
25 off above the connector to allow the connector to lift off of the barbed stumps away from the patient. Thus, the pain and discomfort associated with such central line catheters is avoided, while at the same time providing a secure connection.

Brief Description of the Drawings

 Figure 1 is a perspective view of a typical triple-lumen
30 central line catheter having a seat with a pair of suture holes formed therein.

 Figure 2 is a perspective view of the anchor pad of the present invention illustrating a pair of upstanding barbs to receive the suture holes of the connector.

Detailed Description of the Invention

 Referring to Figure 1, there is shown a typical triple-lumen central line catheter 10 of the type manufactured under

the ARROW® brand name. Although the present invention is illustrated and described herein in connection with a triple-lumen catheter, it should be understood that the principles of the invention apply equally well to other types of catheters with various configurations.

5 The triple-lumen catheter 10 of Figure 1 comprises a central planar seat 12 formed of a soft pliable plastic, having a pair of suture holes 14 formed therein. Extending away from the seat in one direction is a cannula 16 which
10 inserts into the injection site 17 in the body of the patient, in accordance with standard catheterization procedures. Extending away from the seat in the opposite direction are three lengths of IV tubing 18, each ending in a standard IV connector 20, such as, for example, a lure-type lock or septum
15 cap. These standard IV connectors 20 can receive compatible connectors (not shown) formed on the end of IV supply tubing, or can receive manual injections for administering medication or other fluids directly into a central vein of the patient.

20 In order to secure the triple-lumen catheter 10 at the injection site, the seat 12 is typically positioned on the body and sutured to the skin of the patient by means of the suture holes 14. Over time, however, as explained above, the sutures either loosen or tear completely through the seat material. The patient experiences pain and discomfort, and
25 risks infection as a result.

Referring to Figure 2, there is shown the anchor pad 22 of the present invention comprising a planar pad 24 having a self-adhesive material applied to the bottom surface 26
30 thereof. The adhesive secures the anchor pad 22 to the patient's body without sutures.

A pair of barbed uprights 28 integrally mount on the opposite side 24 of the pad 22. The barbs 28 are spaced and configured to receive the suture holes 14 on the seat 12 of the triple-lumen catheter 10 (shown in Figure 1). In
35 addition, the diameter of the cylindrical portion of the uprights (not including the barbs) is sized to slightly deform

the seat of the connector as it press fits onto the pad. Preferably, the seat deforms elastically to be securely retained on the anchor pad.

5 It will be noted that the barbs 28 elastically permit the seat 12 to pass down over the jagged edges of the barbs, but prevent movement of the seat in the opposite direction. Thus, the anchor pad of the present invention securely mounts the seat of the triple-lumen catheter on the patient's body. Not only is the patient relieved of pain, but the risk of complete or partial disengagement is eliminated.

10 In order to remove the catheter, the barbs are simply snapped off so that the seat can be easily lifted over the remaining stumps. The pad is then removed from the patient with minimal discomfort. The barbs are constructed from a material which is less elastic than the material comprising the connector seat but which is easily severable.

15 Therefore, the anchor pad of the present invention presents a significant advance in the use and attachment of central line catheters. While the preferred arrangement of the present invention has been illustrated and described, it should be understood that various changes and modifications to the system illustrated will readily come to mind which fall within the scope of the invention as set forth in the appended claims.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS: -

1. An anchoring apparatus for securing a connector of a catheterization system to a body of a patient, wherein said catheterization connector comprises a substantially planar seat having holes formed therein of the type used for suturing, said anchoring apparatus characterized by:

an adhesive member for secure attachment to the body of the patient; and

at least one retention member mounted on said adhesive member and configured to insert through a corresponding hole of the connector seat and to engage with the connector seat about the hole to prevent accidental disengagement of the catheterization connector from said adhesive member, whereby the connector seat is attached to the adhesive member.

2. The apparatus of Claim 1, further characterized in that said retention member is barbed.

3. The apparatus as defined in Claims 1 or 2, further characterized in that said apparatus includes a plurality of retention members positioned on said adhesive member, said retention members being spaced apart from one another such that the spacing between a plurality of retention members corresponds to the spacing between a corresponding plurality of holes of the connector seat.

4. The apparatus as claimed in Claim 1 or any one of Claims 2-3 when dependent therefrom, further characterized in



that the diameter of said retention member is slightly larger than that of said hole.

5 5. A method for anchoring a connector of a catheterization system to a body of a patient, wherein said catheterization connector includes a substantially planar seat having holes formed therein of the type used for suturing, said method characterized by the steps of:

10 providing an anchoring apparatus having an adhesive member and at least one retention member, said retention member extending outwardly away from said adhesive member;

15 placing said adhesive member on a patient body to secure said anchoring apparatus thereon with said retention member extending away from the patient body; and

20 inserting said retention member through said hole of said connector planar seat to prevent unintentional disengagement between the retention member and the planar seat of the catheterization connector.

25 6. A method of Claim 5, further characterized by the step of configuring said retention member with a plurality of barbs.

7. A method of Claim 6, further characterized by the step of configuring said barbs to extend outwardly from a stem of said retention member in a direction toward said adhesive member.



8. A method of Claim 6, further characterized in that said step of inserting said retention member through said hole comprises the step of elastically deforming said barbs of said retention member to permit said retention member to
5 insert into said hole but to prevent said retention member from extracting from said hole.

9. The method as claimed in Claim 5 or any one of Claims 6-8 when dependent therefrom, further characterized by the steps of:

10 providing a plurality of retention members corresponding to the number of holes in said catheterization connector; and

15 positioning said retention members on said anchoring apparatus such that the position of said retention members correspond with the hole positions in said catheterization connector.

20 10. The method as claimed in Claim 5 or any one of Claims 6-8 when dependent therefrom, further characterized by the step of severing the retention member between said adhesive member and said connector to permit disengagement between said connector and said adhesive member.



11. An anchoring apparatus for securing a connector of a catheterization system to a body of a patient substantially as hereinbefore described with reference to Fig.2 of the accompany drawings.

5 12. A method for anchoring a connector of a catheterization system to a body of a patient substantially as hereinbefore described described with reference to the accompanying drawings.

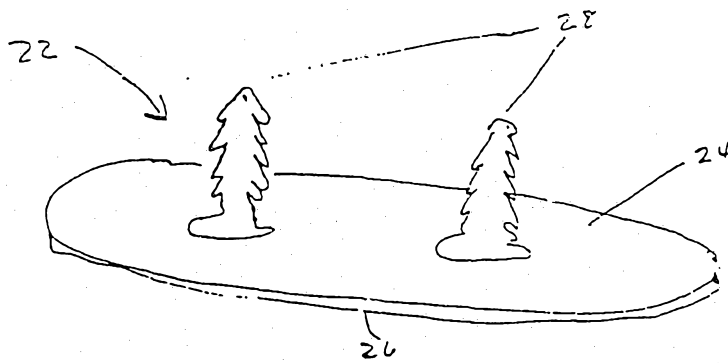
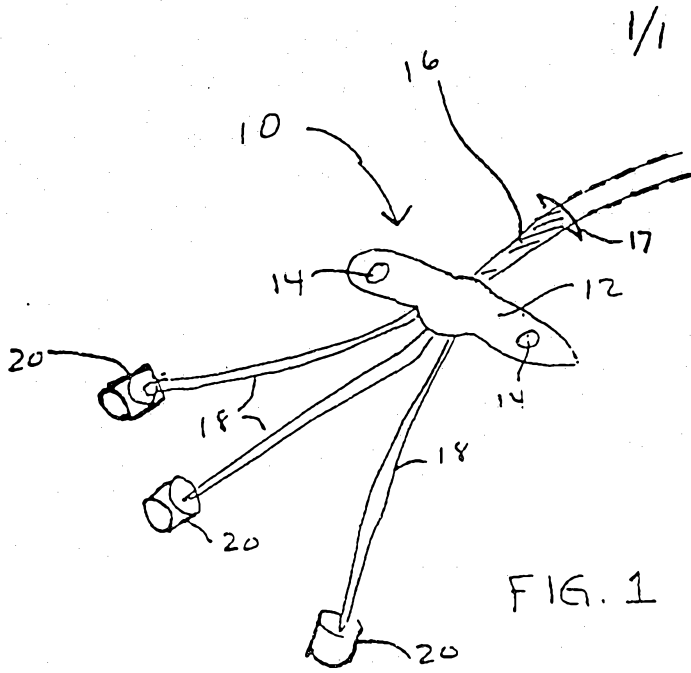
DATED this 20th day of February 1995

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Applicant:

F.B. RICE & CO.



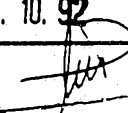
20276/A2



INTERNATIONAL SEARCH REPORT

PCT/US 92/03923

International Application N

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC Int.Cl. 5 A61M25/02		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. 5	A61M	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ^o	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	FR,A,2 381 529 (TAUT, INC.) 22 September 1978 see page 1, line 34 - page 2, line 15; figures ---	1-8
A	WO,A,8 001 458 (WHITMAN MEDICAL CORP.) 24 July 1980 see abstract; figures ---	1-8
A	US,A,4 857 058 (PAYTON HUGH W.) 15 August 1989 see abstract; figures ---	1-8
A	EP,A,0 064 284 (NESSLER) 10 November 1982 see page 4, last paragraph - page 5, last paragraph; figures ---	1-8
-/--		
<p>^o Special categories of cited documents :¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"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</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
17 SEPTEMBER 1992	0 6. 10. 92	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	MIR Y GUILLEN V. 	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	US,A,3 602 227 (ANDREW) 31 August 1971 see abstract; figures 1-4 -----	8

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

US 9203923
SA 60760

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 17/09/92

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A-2381529	22-09-78	US-A- 4129128	12-12-78
		BE-A- 864259	16-06-78
		CA-A- 1133781	19-10-82
		DE-A- 2803395	24-08-78
		JP-A- 53115597	09-10-78

WO-A-8001458	24-07-80	US-A- 4224937	30-09-80
		US-A- 4250880	17-02-81
		BE-A- 887056	04-05-81
		EP-A- 0022846	28-01-81
		US-A- 4397647	09-08-83

US-A-4857058	15-08-89	None	

EP-A-0064284	10-11-82	DE-A- 3117416	18-11-82

US-A-3602227	31-08-71	None	
