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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 August 2006 (10.08.2006)

PCT

(10) International Publication Number
WO 2006/082607 A1

(51) International Patent Classification:
A61M 25/06 (2006.01)

(21) International Application Number:
PCT/IT2006/000028

(22) International Filing Date: 18 January 2006 (18.01.2006)

(25) Filing Language: Italian

(26) Publication Language: English

(30) Priority Data:
RC2005A000001 3 February 2005 (03.02.2005) IT

(71) Applicant *(for all designated States except US)*: **MEDILINE SRL** [IT/IT]; Via Trapezzoli, 44, I-89068 Frazione San Gregorio Reggio Calabria (IT).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **CUZZUCOLI, Antonino** [IT/IT]; Via Trapezzoli, 44, I-89068 Frazione San Gregorio Reggio Calabria (IT).

(74) Agent: **SARPI, Maurizio**; Studio Ferrario, Via Collina, 36, I-000187 Roma (IT).

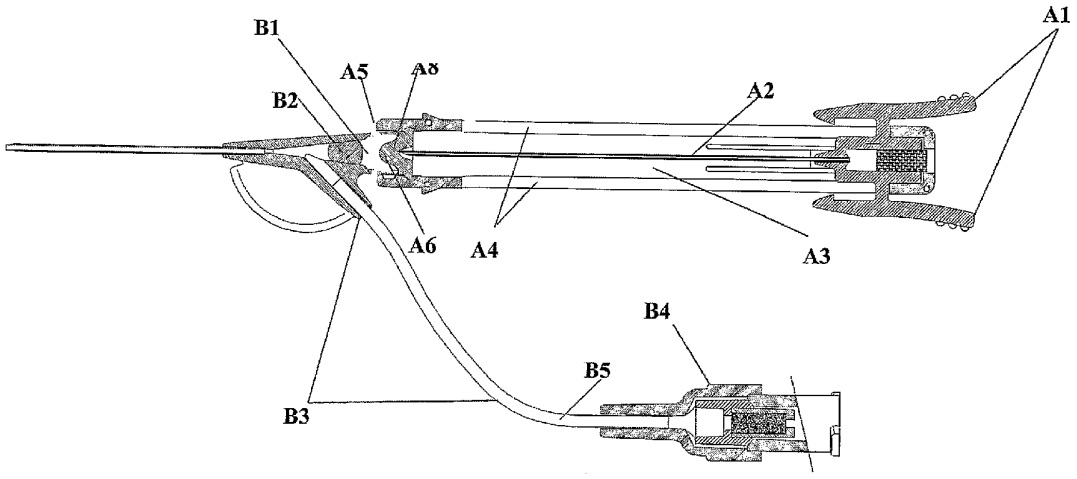
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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

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

(54) Title: MEDICAL DEVICE FOR TWO-WAY INFUSION



(57) Abstract: The present invention relates to a device for two-way infusion essentially- comprising: a catheter (C2) with a needle (A2) slidable insertable therein, protection means for the needle after the insertion of the catheter into a blood vessel, protection means against blood reflux to the outside, and an infusion chamber.

WO 2006/082607 A1

Improved medical device for two-way infusion

The present invention concerns the medical-sanitary field and particularly relates to a device to be used for the vein and/or artery encannulation characterized by particular protection means ensuring a better safety for the operators.

The products which are presently on the market and used for the same purpose do not protect the medical staff and/or patients from possible infections by infected blood even if such products have reached a high degree of functionality as far as the penetration of the needle into the blood vessels and the handiness of the equipment is concerned.

An encannulation procedure is essentially characterized by three important steps:

1) insertion of the catheter of the device into the vein/artery;

2) extraction of the needle/spindle from the catheter;

3) connection of the catheter to an infusion and/or a blood sample taking system.

The greater risks of catching infections are inherent in the second and third step, i.e. upon extracting the needle from the catheter. In fact, during such operation (second step) the needle itself can easily cause a fortuitous puncture and/or leakage of blood from its cavity with consequent possible infections. The channel with the catheter in situ which meanwhile is set free of the just extracted needle/spindle causes blood to flow back to the outside so that the contact with the latter is unavoidable during the

connection of the catheter to the typical infusion devices (third step).

It is then inferred that this procedure executed especially on patients for whom a diagnosis has not been made yet is potentially a high risk of infection for the medical staff.

The main object of the present invention is to strongly reduce the fortuitous infection risk by infected blood described above.

This has been accomplished according to the invention by providing a device for two-way infusion essentially comprising: protection means for the cannula-needle after the insertion of the catheter into the blood vessel, protection means against blood reflux to the outside, and an infusion chamber with intravenous-intraarterial catheter.

A better understanding of the invention will result from the following detailed description with reference to the accompanying drawings that show a preferred embodiments thereof only by way of a not limiting example.

In the drawings:

Figure 1 is an exploded view of the invention, in longitudinal section;

Figure 2 is a longitudinal section view similar to the previous one showing the device assembled and ready for encannulation.

With reference to the figures, said protection means

for the cannula-needle according to the present invention includes a display chamber C3 of preferably plastic, transparent material with sliding self-locking, elastic tabs A1 which are axially integral with the proximal end of hollow needle/spindle A2.

In the preferred embodiment disclosed said display chamber C3 is inserted into a protection capsule A3 consisting of a cylinder body of preferably plastic, transparent material with two side recesses A4 along which both self-locking tabs A1 that can be operated manually and display chamber C3 are able to slide.

At the distal end, capsule A3 is provided with self-tightening bayonet coupling means A5 able to perform a dual function:

- housing a thermoplastic rubber seal A6 with the purpose of incorporating the point of needle A2 when retracted, and at the same time avoiding any blood leakage;
- connecting the capsule to the infusion chamber.

As the device is arranged to be inserted into a vein (Fig. 2) display chamber C3 with tabs A1 is blocked at the distal end of protection capsule A3 by suitable anchor clamps C1, while the point of needle A2 comes out of intravenous catheter C2 and the device is thus ready for encannulation.

The blood reflux within display chamber C3 indicates that the vein/artery is perfectly cannulized, whereupon needle A2 is fully retracted by means of the two tabs A1 until the proximal self-locking position (Fig. 1) and there clamped by suitable check clips C4.

Advantageously, the body of the needle is fully housed within protection capsule A3 and the point of the

needle is incorporated within the central body A8 of seal A6, thus avoiding that the blood inside the needle/spindle comes out to the outside.

At this point, capsule A3 containing the needle may be removed under safety conditions by operating the self-locking bayonet coupling means A5, leaving in situ only the infusion chamber connected to catheter C2.

A second peculiar feature of the present invention consists in that the main access B1 to the infusion chamber of the known devices is closed in the present invention by a plug B2 of thermoplastic material or silicone that can be pierced and is able to avoid the blood reflux to the outside.

According to a further peculiar feature of the invention the infusion chamber is provided with a side access B3 which is connected by a suitable pipe B5 to a check valve B4 with water-repellent filter which guarantees residual air within pipe B5 to be expelled and at the same time the reflux blood to be confined therein once the needle is extracted from the catheter.

It is self-evident from the foregoing that the invention guarantees the infusion and/or blood taking operations to be carried out through said side access B3 and the relative pipe B5. In fact, the connection of any connection line (phleboclysis, syringe cone, etc.) to check valve B4 causes the valve to open automatically and to start the bi-directional flow accordingly. The latter feature together with the particular protection of the needle makes the use of the device really safe.

The present invention has been described and

illustrated according to a preferred embodiment thereof, however, it is self-evident that those skilled in the art can make technically and/or functionally equivalent modifications and/or replacements without departing from the scope of the present industrial invention.

Claims

1. A device for intravenous encannulation or catheter-needle of the type including a catheter (C2) and a needle/spindle (A2) inserted therein, characterized in that there is provided in combination:

- protection means for the cannula-needle (A2) after the insertion of catheter (C2) into the blood vessel and the following retraction of needle (A2) from catheter (C2);
- protection means against blood reflux to the outside;
- an infusion chamber with intravenous-intraarterial catheter (C2).

2. The device according to the preceding claim, characterized in that said protection means for the cannula-needle (A2) after its retraction from catheter (C2) can be removed.

3. The device according to claim 1, characterized in that said protection means for the cannula-needle (A2) includes a display chamber (C3) of transparent material with sliding self-locking, elastic tabs (A1), said display chamber and said tabs being axially integral with the proximal end of hollow needle/spindle (A2).

4. The device according to the preceding claim, characterized in that said display chamber (C3) is inserted into a protection capsule (A3) consisting of a cylinder body of preferably plastic, transparent

material with two side recesses (A4) along which both self-locking tabs (A1) that can be operated manually are able to slide.

5. The device according to the preceding claim, characterized in that the distal end of capsule (A3) is provided with self-tightening bayonet coupling means (A5).

6. The device according to the preceding claim, characterized in that said bayonet coupling means (A5) are capable of:

- housing a thermoplastic rubber seal (A6) with the purpose of incorporating the point of needle (A2) when retracted, and at the same time avoiding any blood leakage from the cavity of the needle/spindle;
- connecting capsule (A3) to the infusion chamber.

7. The device according to the preceding claim, characterized in that as the device is arranged to be inserted into a vein for encannulation, display chamber (C3) with tabs (A1) is able to be blocked at the distal end of protection capsule (A3) by suitable anchor clamps (C1), while the point of needle (A2) comes out of intravenous catheter (C2).

8. The device according to the preceding claim, characterized in that as the blood reflux to display chamber (C3) indicates that the vein/artery is perfectly cannulized, needle (A2) is able to be fully retracted by means of the two tabs (A1) until a proximal self-locking position.

9. The device according to the preceding claim, characterized in that there are provided suitable check clips (C4) able to block the fully extracted needle, thus providing that the body of the needle is fully housed inside protection capsule (A3) and the point of the needle is incorporated within the central body (A8) of seal (A6), thus avoiding that the blood inside the needle/spindle comes out to the outside.

10. The device according to the preceding claim, characterized in that capsule (A3) containing the needle may be removed by operating the self-locking bayonet coupling means (A5), leaving in situ only the infusion chamber connected to catheter (C2).

11. The device according to claim 1, characterized in that said infusion chamber is closed by a plug (B2) of thermoplastic material or silicone that can be pierced and is able to avoid the blood reflux to the outside.

12. The device according to any preceding claim, characterized in that said infusion chamber is provided with a side access (B3) which is connected by a suitable pipe (B5) to a check valve (B4) with water-repellent filter which guarantees residual air within pipe (B5) to be expelled and at the same time the reflux blood to be confined therein once needle (A2) is extracted from catheter (C2).

13. The device according to claim 4, characterized in that said display chamber (C3) and said protection

capsule (A3) are of plastic material.

14. A device for intravenous encannulation as essentially described and illustrated in the present description and the accompanying drawings.

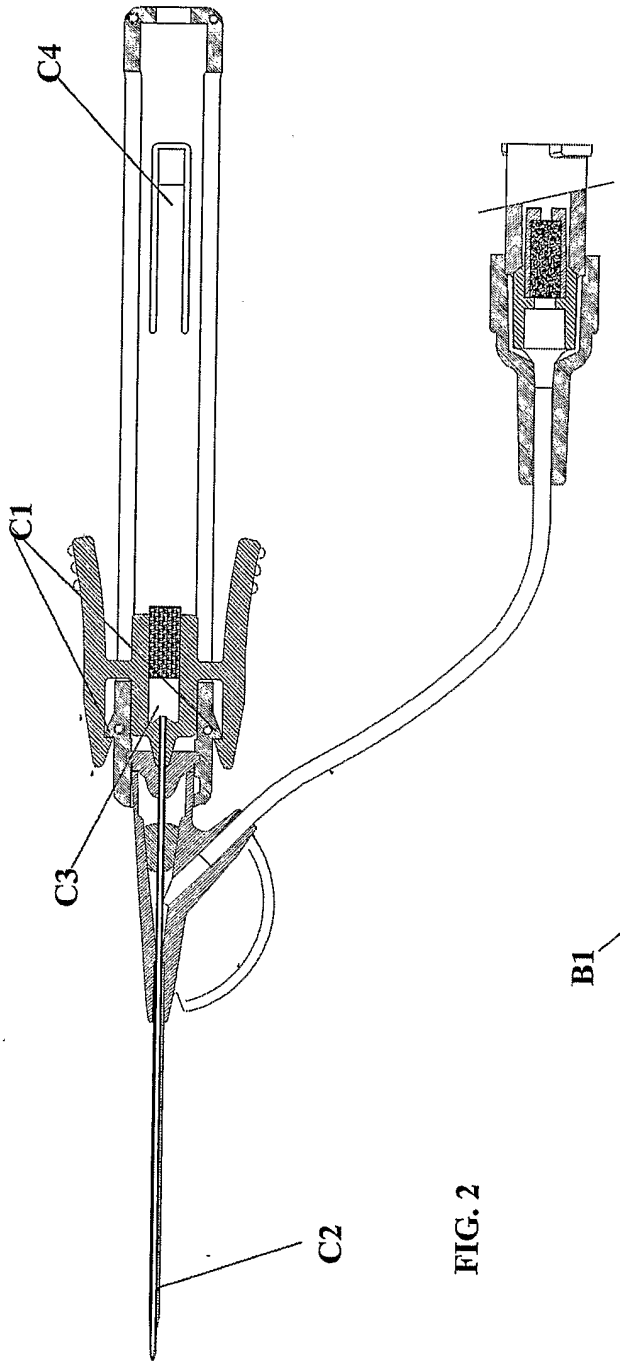


FIG. 2

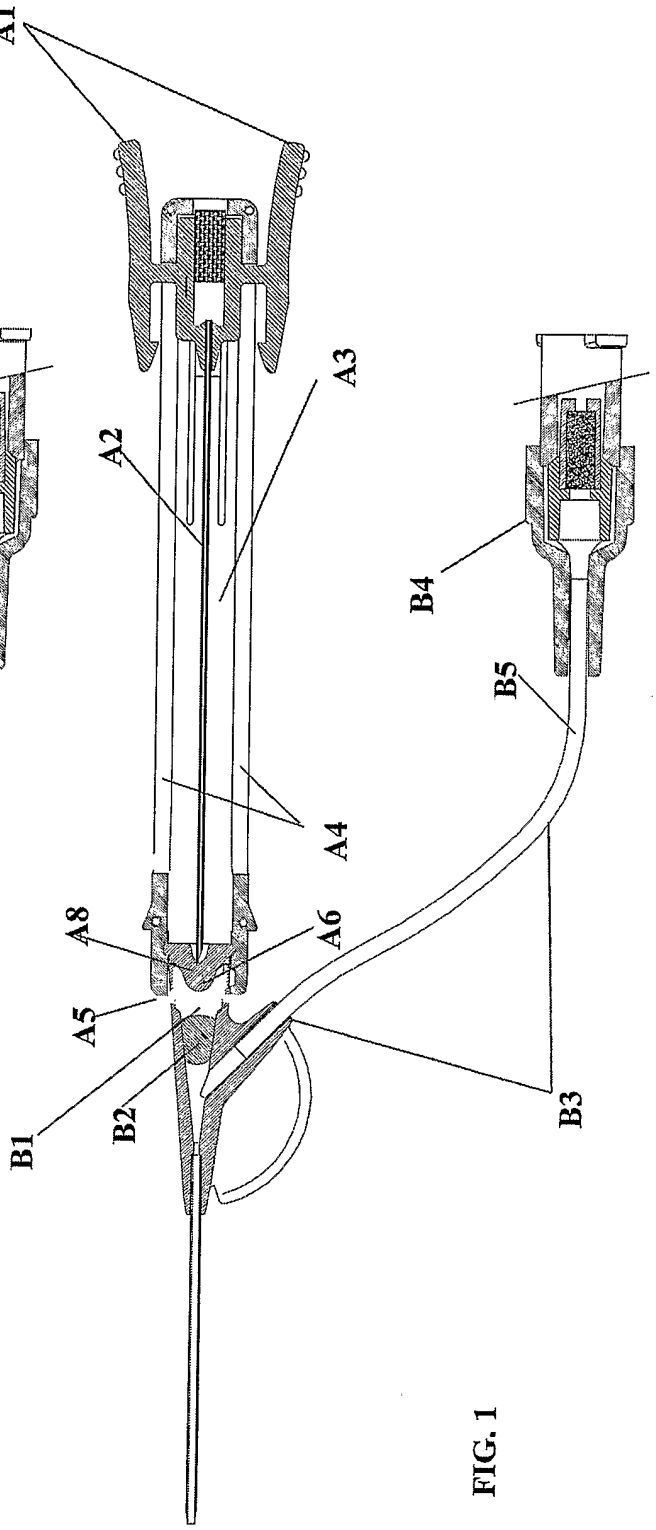


FIG. 1

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2006/000028

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 954 698 A (PIKE ET AL) 21 September 1999 (1999-09-21) the whole document	1-5,11, 13 6-10,12
X Y	WO 00/56388 A (ANGLO OPERATIONS LIMITED; HARRISON, PETER, HUGH; BLAKE, WILLIAM, ALLEY) 28 September 2000 (2000-09-28) the whole document	1-5,11, 13 6-10,12
Y	US 5 911 705 A (HOWELL ET AL) 15 June 1999 (1999-06-15) column 3, lines 24-36 column 4, lines 17-27; figures 4-6	1-13
Y	US 6 213 978 B1 (VOYTEN CHERIE A) 10 April 2001 (2001-04-10) column 4, line 38 - column 6, line 67; figures 2,4	1-13

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 May 2006	29/05/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Ceccarelli, D

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2006/000028

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97/45151 A (CUPPY, MICHAEL, J) 4 December 1997 (1997-12-04) abstract; figures 14-16	1,2,11, 12
A	US 4 966 586 A (VAILLANCOURT ET AL) 30 October 1990 (1990-10-30) figures 9A-9C	5

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IT2006/000028

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 14
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 14

Claim 14 has been defined only with a generic reference to the whole description and drawings. The scope of the claim is therefore completely unclear and cannot be searched.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IT2006/000028

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5954698 A	21-09-1999	DE 69831317 D1	29-09-2005
		EP 0964716 A1	22-12-1999
		ES 2244044 T3	01-12-2005
		JP 2001508678 T	03-07-2001
		WO 9830268 A1	16-07-1998
WO 0056388 A	28-09-2000	AU 4861100 A	09-10-2000
US 5911705 A	15-06-1999	CA 2201055 A1	04-10-1997
		EP 0799626 A1	08-10-1997
		JP 2962268 B2	12-10-1999
		JP 10015075 A	20-01-1998
		US 5865806 A	02-02-1999
US 6213978 B1	10-04-2001	NONE	
WO 9745151 A	04-12-1997	AT 264699 T	15-05-2004
		AU 3370397 A	05-01-1998
		CA 2228264 A1	04-12-1997
		DE 69728740 D1	27-05-2004
		DE 69728740 T2	28-04-2005
		EP 0847289 A1	17-06-1998
US 4966586 A	30-10-1990	NONE	