P/00/008
Section 29(1)
Regulation 3.1(2)

676857

AUSTRALIA
Patents Act 1990

NOTICE OF ENTITLEMENT

We WHITE SPOT AG

of Aegeristrasse 35, CH-6342 BAAR, SWITZERLAND

being the Applicant and Nominated Person, in respect of Application No. 67926/94, entitled, "Use of and Process for the Introduction of Fibrin Sealant into a Puncture Channel", state the following:

Oskar E Illi is th actual inventor of the invention the subject of the Application.

The applicant and nominated person would be entitled to have assigned to it a patent granted to the actual inventor.

WHITE SPOT AG is the applicant of the application listed in the declaration under Article 8 of the PCT.

Convention priority is claimed from the following basic application referred to in the declaration under Article 8 of the PCT:

Basic Applicant	Application Number	Application Date	Country	Country Code
WHITE SPOT AG	1792/93-4	16 June 1993	Switzerland	CH

The basic application referred to in the declaration under Article 8 of the PCT was the first application made in a Convention country in respect of the invention the subject of the Application.

DATED this 29th day of November 1996

WHITE SPOT AG
By their Patent Attorney

GRIFFITH HACK

OUR REF: P23695A GS/kls

AU9467926

(12) PATENT ABRIDGMENT (11) Document No. AU-B-67926/94
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 676057

(54) Title
USE OF AND PROCESS FOR THE INTRODUCTION OF FIBRIN SEALANT INTO A PUNCTURE CHANNEL

International Patent Classification(s)
(51)[6] A61B 017/03 A61M 031/00

(21) Application No. : 67926/94 (22) Application Date : 09.06.94

(87) PCT Publication Number : WO94/28798

(30) Priority Data

(31) Number	(32) Date	(33) Country
1792/93	16.06.93	CH SWITZERLAND

(43) Publication Date : 03.01.95

(44) Publication Date of Accepted Application : 27.02.97

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(56) Prior Art Documents
US 4202332
EP 482350

(57) Claim

1. A device for introducing a two-component fibrin sealant into a puncture channel in the vicinity of an arterial or venous puncture point, comprising a sealing cannula and a working cannula extending axially therethrough, the working cannular being used for the intravascular introduction of instruments into a vessel, wherein a gap is provided between the working cannular and the sealing cannula through which the fibrin sealant can be passed from a connector disposed towards one end of the sealing cannula to one or more outlet openings in the sealing cannula, said one or more openings being disposed towards and spaced apart from another end of the sealing cannular, and the gap being closed by means disposed between the another end of the sealing cannular and the one or more openings.

OPI DATE 03/01/95 APPLN. ID 67926/94
AOJP DATE 09/02/95 PCT NUMBER PCT/CH94/00114

AU9467926

(51) Internationale Patentklassifikation 5 : A61B 17/00

A1

(11) Internationale Veröffentlichungsnummer: WO 94/28798

(43) Internationales Veröffentlichungsdatum: 22. December 1994 (22.12.94)

(21) Internationales Aktenzeichen: PCT/CH94/00114

(22) Internationales Anmeldedatum: 9. Juni 1994 (09.06.94)

(30) Prioritätsdaten:
1792/93-4 16. Juni 1993 (16.06.93) CH

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(81) Bestimmungsstaaten: AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, HU, JP, KE, KP, KR, KZ, LK, LU, LV, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TT, UA, US, VN, europäisches Patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI Patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Veröffentlicht
Mit internationalem Recherchenbericht.
Mit geänderten Ansprüchen.

676057

(54) Title: USE OF AND PROCESS FOR THE INTRODUCTION OF FIBRIN SEALANT INTO A PUNCTURE CHANNEL

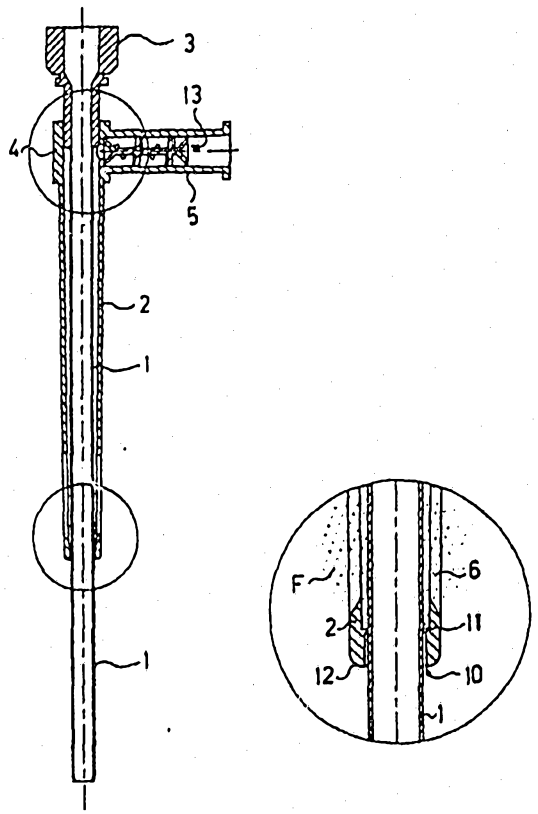
(54) Bezeichnung: VERWENDUNG VON UND VORRICHTUNG ZUM EINBRINGEN VON FIBRINKLEBER IN EINEN STICHKANAL

(57) Abstract

Following an intravascular operation, the puncture channel is sealed as near to the vessel as possible with a two-part fibrin sealant. This is done by means of a device which comprises a sealing cannula (2) longitudinally transfixed by the working cannula (1). Either the working cannula (1) or the sealing cannula (2) is fitted with a medical connector (3). The sealing cannula (2) has a reinforced sleeve (4) with a connecting stub (5) in which the two fibrin sealant components are mixed (13) and introduced into the axial gap between the working and sealing cannulas. The fibrin sealant (F) is taken to the region of the vessel to be sealed via radial outlets (6).

(57) Zusammenfassung

Nach einem intravasalen Eingriff wird der Stichkanal mit einem Zweikomponenten-Fibrinkleber möglichst gefässnah versiegelt. Dies geschieht mit einer Vorrichtung, die eine Versiegelungskanüle (2) umfasst, welche von der Arbeitskanüle (1) in Längsrichtung durchsetzt wird. Entweder die Arbeitskanüle (1) oder die Versiegelungskanüle (2) sind mit einer Medizinalkupplung (3) versehen. Die Versiegelungskanüle (2) hat eine verstärkte Manschette (4) mit einem Anschlussstutzen (5), in dem die beiden Fibrinkleberkomponenten vermischt (13) und in den achsialen Zwischenraum zwischen der Arbeitskanüle und der Versiegelungskanüle geleitet werden. Über radiale Austrittsöffnungen (6) wird der Fibrinkleber (F) in den Bereich des zu versiegelnden Gefässes gebracht.



USE OF AND PROCESS FOR THE INTRODUCTION OF FIBRIN SEALANT INTO A PUNCTURE CHANNEL

The present invention relates to the use of endogenous blood coagulants obtained from plasma protein in the form of a two-component fibrin sealant, whose components are mixed at the instant they are delivered.

The invention also relates to a device for introducing the two-component fibrin sealant into a puncture channel in the vicinity of an arterial or venous puncture point.

Many operations in human or veterinary medicine require puncturing of vessels. With percutaneous transluminar coronary angioplasty (PTCA), heart operations and catheterizations of the heart in particular it is necessary to close the punctured vessels again with great care. In most cases this is performed by means of direct compression of up to one hour and a compression bandage which must be applied up to 24 hours and requires hospitalization of one to two days. Accordingly there is the desire to find a solution leading to a more rapid and secure closure of the puncture point.

A method by the name of Vasoseal was introduced during a meeting of the American Heart Association on 11. 17. 1992 in New Orleans. With this method respectively two collagen plugs made of bovine collagen were pushed into the puncture channel as far as the puncture point. It was noted during the said meeting that, besides the somewhat rare rejection reaction of the exogenous collagen, there are various other disadvantages or risks. It was noted that this system is ineffective in many cases and that there is a certain danger of emboli. In approximately 46% of all cases hematomas of an order of magnitude between 2 to 6 cm were formed. Weeks or months go by before the bovine collagen is completely resorbed. In addition, the method leads to increased scar

formation which makes an ultrasonic examination more difficult. Finally, although hospitalization did not become superfluous, it was reduced by at least 24 hours. However, one of the most essential problems lies in the handling, i.e. the introduction of the collagen plugs into the puncture channel. Since it is necessary to push two college plugs successively into the puncture channel, the user finds the penetration depth, for example, hard to determine. If the collagen plugs are pushed in too deeply it is possible that the collagen plug is pushed through the puncture point into the vessel, which would result in an obstruction or in the vessel itself being pushed closed.

It is an object of the present invention to provide a novel method to close such puncture points rapidly, dependably and without one or more of the above mentioned disadvantages.

It has been shown that when endogenous blood coagulants obtained from plasma protein in the form of a two-component fibrin sealant, whose components are mixed at the instant they are delivered, are used and this mixture is introduced into a puncture channel as close as possible to a vessel during or directly following an intravascular intervention, an optimal vessel seal is created. Histological tests have proven these facts.

Accordingly, the present invention provides a device for introducing a two-component fibrin sealant into a puncture channel in the vicinity of an arterial or venous puncture point, comprising a sealing cannula and a working cannula extending axially therethrough, the working cannular being used for the intravascular introduction of instruments into a vessel, wherein a gap is provided between the working cannular and the sealing cannula through which the fibrin sealant can be passed from a connector disposed towards one end of the sealing cannula to one or more outlet openings in the sealing cannula, said one or more openings being disposed towards and spaced apart from another end of the sealing

cannular, and the gap being closed by means disposed between the another end of the sealing cannular and the one or more openings.

Preferably, the sealing cannula is provided with a reinforced cuff formed as one piece on the one end.

It is preferred that the connector is laterally formed as one piece on the reinforced cuff. Alternatively, the connector may be manufactured separately and attached to the reinforced cuff.

Preferably, a mixing element is located in the connector. The sealing cannular may taper from one inner diameter towards the connector to a shorter inner diameter toward the outlet opening or openings. Preferably, the outlet opening or openings are in the form of a slit or slits extending longitudinally of the sealing cannula.

It is preferred that the sealing cannula is provided with a plurality of inwardly oriented axially extending support ribs to provide said gap.

Preferably the sealing cannula is also provided with an annular sealing bead at its another end.

In other embodiments the sealing cannula is closed at the one end by means of a lead-in plug, in which a tube-shaped support envelope is sealed, which itself in turn extends through the entire sealing cannula and is sealed at the another end of the sealing cannula, and that the working cannula is guided freely movable in the support envelope, so that the fibrin sealant can flow in the gap between the supporting envelope and the sealing cannula from the connector as far as the one or more outlet openings.

Preferably, the support envelope is provided with a plurality of stiffening ribs which are directed radially outward and directed toward an inner wall of the sealing cannula.

Preferably further the sealing cannula has an abruptly widening rounded head at its another end where the working cannula emerges from the sealing cannula.

It is preferred that the head has a axially extending annular sealing lip seated on the working cannula.

Two preferred exemplary embodiments of the device of the invention are explained with reference to the accompanying drawings in which:

Fig. 1 is a side elevation of a first embodiment of the device of the invention;

Fig. 2 is a cross sectional view through the device of Fig. 1 along the line II - II on an enlarged scale;

Fig. 3 is an axial longitudinal section through the embodiment of Fig. 1;

Fig. 4 is an enlarged section of the device in the area of the connector;

Fig. 5 is an enlarged section in the area of the exit of the working cannula from the sealing cannula;

Fig. 6 shows a side elevation view of a second embodiment of the device;

Fig. 7 is a cross section through this device along the line VII - VII of Fig. 6;

Fig. 8 is an axial longitudinal section through the device of Fig. 6;

Fig. 9 is an enlarged section of the drawing of Fig. 8 in the area of the connector; and

Fig. 10 illustrates an enlarged section of the drawings of Fig. 8 in the area of the exit of the working cannula from the sealing cannula.

In what follows, first he two preferred embodiments of the device of the invention and then their manipulation and the general employment of fibrin sealant for sealing a puncture point in a vessel will be shown. The simpler embodiment of the device in accordance with Figs. 1 to 5 consists of only three elements which can be put together. The working cannula, also called worksheet in technical language, is identified by the reference numeral 1. The working cannula itself is simply a small cylindrical tube open at both ends, made of plastic. Its front end 1' is used for introducing the cannula through

the puncture point into the opened blood vessel. The working cannula is relatively thin-walled and therefore has a certain amount of bending flexibility. In this embodiment the working cannula 1 is fixedly connected with a Medical coupling 3 at the other end, the rear end. The actual medical coupling 3 can be a known Luer locking coupling, for example. An exactly fashioned muff 3' is formed in an interlocking and sealing manner on the actual medical coupling 3. The working cannula 1 axially extends in the longitudinal direction through a sealing cannula 2 and at the bottom projects for some distance out of the sealing cannula. The sealing cannula 2 itself is also again embodied in the shape of a small concentric tube, but its exterior diameter, and preferably also its interior diameter, decrease from the top to the bottom, i.e. the interior diameter is reduced from the side where the medical coupling 3 is inserted to the lower end where the working cannula emerges from the sealing cannula 2.

Thus a gap in the form of a hollow space 7 remains between the working cannula and the sealing cannula over the entire length on which the working cannula 1 is concentrically enclosed by the sealing cannula 2. The sealing cannula 2 has a reinforced cuff 4 at the

upper end, which has a considerably greater wall thickness than the wall thickness of the sealing cannula 2. A connector 5 terminates in the sealing cannula 2 in the area of the reinforced cuff 4. A two-component fibrin sealant can be introduced into the hollow space between the working cannula and the sealing cannula through this connector 5. The fibrin sealant can exit from the hollow space 7 only through the outlet opening 6 in the lower area of the sealing cannula 2. So that fibrin sealant does not unintentionally enter the blood vessel, the outlet openings 6 are at least approximately radially oriented toward the outside. Of course, by radially not only the direction, interpreted in a strictly geometric sense, is meant. Instead this is only intended to express that the outflow direction is not axial. The functioning of the device is of course already assured by means of a single outlet opening, but preferably several outlet openings 6 distributed over the circumference will be provided. Also, in principle the form of the embodiment of the outlet openings 6 can be freely designed. However, for technical production reasons they will be formed in the shape of several linear slits distributed over the circumference.

To form an exact receptacle 15 for the medical coupling 3, the upper opening of the sealing cannula 2 must be provided with a snug fit.

For sealing the working cannula 1 against the sealing cannula 2 in the area of the through-opening 10, an annular sealing bead or sealing rib 11, which is oriented radially inward and sealingly rests on the outer surface of the working cannula 1, is disposed in the through-opening 10.

Although in a preferred manner the connector 5 is formed in one piece directly on the sealing cannula 2 in the area of the

reinforced cuff, it is of course also possible to manufacture the connector separately and to connect it later with the sealing cannula by means of a screw thread 17. In place of the screw connection 17, a welded or adhesive connection is of course also conceivable. Mixing elements are already available on the market for mixing the two components of the two-component fibrin sealant. Therefore, for reasons of cost the connector 5 would be sized in such a way that an already available mixing element 13 can be inserted into it.

As already mentioned, the wall thickness of the working cannula 1 is very little. Preferably it is only a few tenths of a millimeter. The hollow space 7 remaining concentrically around the working cannula 1 between its outer wall and the inner wall of the sealing cannula 2 is of extremely small dimensions. Since all of the surgical instruments must be inserted and removed though the working cannula 1, it is of advantage to provide means which cause this hollow space 7 to remain continuously open. Support ribs 9 which preferably extend axially are disposed on the inner wall of the sealing cannula 2 for this purpose.

The support ribs 9 also result in a stiffening of the also thin-walled sealing cannula 2. By means of this the danger is removed that a slight contraction of the muscular tissue through which the sealing cannula extends leads to a deformation of the sealing cannula 2 which could close the hollow space 7. In this way the required through-opening for the fibrin sealant is assured in any case. The second preferred embodiment of the device of the invention for introducing two-component fibrin sealant through a puncture channel into the vicinity of an arterial or venous puncture point is illustrated in Figs. 6 to 10. While with the first embodiment the working cannula 1 with the associated medical

coupling 3 must be exactly adapted to the sealing cannula for a sealing connection, with the second embodiment it is possible to use a commercially available working cannula with an arbitrary medical coupling 3. In this case a sealing connection between the medical coupling 3 and the sealing cannula 2 is omitted.

Hardly any difference can be seen in the exterior shape of the two devices. Accordingly, identical parts have been given the same reference numerals in both embodiments. Here, too, the working cannula 1 completely extends in the axial direction through the sealing cannula 2. However, the medical coupling 3 fixedly disposed on the working cannula 1 does not enter the sealing cannula 2, but is located shortly above it. The lower end of the working cannula 1' again is embodied to be conical.

The sealing cannula 2 again has a reinforced cuff 4 at its upper end. Here, too, a connector 5 terminates into the interior of the sealing cannula 2 in the area of the reinforced cuff 4. At is lower end, i.e. in the area shortly above the through-opening 10, it also has an outlet opening 6 directed approximately radially outward. Here, too, several outlet opening 6 are disposed evenly distributed over the circumference, which again are embodied slit-like. The essential difference between this embodiment and the previously described embodiment can be seen in particular in the sectional drawing of Fig. 8. In this case a support envelope 20 is maintained in the sealing cannula 2, which defines a free space 21 between itself and the inner wall of the sealing cannula 2. The working cannula 1 passing through the sealing cannula 2 now extends inside the support envelope 20. The fibrin sealant pressed in through the connector 5 now no longer flows directly between the outer wall of the working cannula 1 and the inner wall of the sealing cannula 2, but instead between the

outer wall of the support envelope 20 and the inner wall of the sealing envelope 2. In the area of the lower outlet opening 10, the sealing cannula 20 is provided with a thickened head area 12. This also applies to the first described embodiment. A concentric groove 23 has been cut into the inside of this thickened head area 12. This groove 23 narrows from top to bottom, so that the support envelope 20 is slightly widened when it is pushed on and comes to rest sealingly in the annular groove 23. The support envelope 23 is maintained at the top in a similar manner in a lead-in plug 18. The lead-in plug 18 has a centered through-bore 24.

The working cannula 1 enters the support envelope 20 through this bore. An annular sealing bead 25 results in a clamping and sealing support of the working cannula 1 in the support envelope 20. The lead-in plug 18 is provided with a collar 25 which, in the assembled state of the lead-in plug, fits completely into a recess in the reinforced cuff 4. The reinforced cuff 4 can be provided with an again reinforced outer diameter in the upper area to obtain a sufficient wall thickness. The lead-in plug 18 is also provided with an annular concentric groove 24, whose diameter widens from the bottom to the top, so that here, too, the slightly widened support envelope 20 is held clampingly and sealingly. As can be clearly seen from Fig. 9, the two-component fibrin sealant enters the free space 21 through the connector 5 in which the mixing element 13 is disposed.

Here, too, is the head area 12 abruptly thickened and rounded. The abrupt thickening is used so that the sealing cannula 2 is not pushed through the puncturing place in the blood vessel into the latter. On the other hand, the rounding is

intended to ease the introduction of the sealing cannula into the puncture channel.

The working cannula 1 is here also sealed against the sealing cannula 2. This is achieved by means of a sealing lip 22 at the end, which rests on the outer wall of the working cannula 1.

However, the function of the annular sealing lip 22 is not the same as that of the sealing bead 11 or the sealing ring, namely for sealing the hollow space of the sealing envelope 2 and therefore to prevent the exit of the fibrin sealant in the axial direction, but is used for preventing the entry of blood into the area between the working cannula 1 and the support envelope 20.

The employment of the device in accordance with the invention will be briefly described. In a first step in the course of catheterization a hollow needle is pushed through the skin and the various tissue layers underneath it up to the blood vessel to be punctured. A guide is pushed into the blood vessel through the hollow needle. Leaving the guide in the introduced position, the hollow needle is retracted over the guide and in place of it a dilator is pushed through the puncture channel into the blood vessel. Afterwards, the working cannula and the sealing cannula are then fed through the dilator, wherein the working cannula is inserted into the blood vessel, while the abruptly thickened head area of the sealing cannula is only pushed in as far as the puncture point. Thus the outlet openings 6 are located above the puncture point of the blood vessel, but inside the puncture channel. The physician now can insert the necessary instruments through the working cannula into the blood vessel. This can be a balloon catheter, a fiber-optical wave guide or the probe of a camera or also other means.

At the end of the operation or examination, first the instruments are pulled out of the vessel through the working cannula and then the two-component fibrin sealant is pressed through the connector 5, the free space 21 or the hollow space 7 and through the outlet openings 6 into the puncture channel. After only a few seconds the fibrin sealant results in coagulation into a fibrin clot of the in the area of the puncture channel or the puncture point, because of which bleeding is completely stopped. The formation of hematomas is entirely prevented. A risk of an embolus could no longer be noted. A one hundred percent effectiveness has been achieved in all tests performed to date. No rejection reactions to the human fibrin sealant were noted. Even with the use of an increased concentration of aprotinin, excellent sealing was obtained in animal tests (dog, minipig).

Hospitalization of the patient can therefore be omitted.

The use of the human two-component fibrin sealant, known for several years, for use in sealing a puncture point or a puncture channel to the puncture point is not known. This novel sealing method by means of the fibrin sealant is in no way obvious, since up to now it had always been assumed that the entry of fibrin sealant into the bloodstream could lead to complications. Only the present applicator permits a danger-free use of the fibrin sealant.

The application in accordance with the invention of the fibrin sealant can also take place without the device of the invention in that the fibrin sealant is directly applied in the puncture channel by means of an injection needle. However, since the exact location of the puncture channel by means of an injection needle is not quite simple, it would be better not to

employ this method. If the injection of the fibrin sealant takes place outside the area of the puncture channel, there will of course be no sealing of the blood vessel.

Surely other embodiments, besides the above described preferred embodiments of the device in accordance with the invention, are conceivable without departing from the basic concept of the invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A device for introducing a two-component fibrin sealant into a puncture channel in the vicinity of an arterial or venous puncture point, comprising a sealing cannula and a working cannula extending axially therethrough, the working cannular being used for the intravascular introduction of instruments into a vessel, wherein a gap is provided between the working cannular and the sealing cannula through which the fibrin sealant can be passed from a connector disposed towards one end of the sealing cannula to one or more outlet openings in the sealing cannula, said one or more openings being disposed towards and spaced apart from another end of the sealing cannular, and the gap being closed by means disposed between the another end of the sealing cannular and the one or more openings.

2. A device in accordance with claim 1, wherein the sealing cannula is provided with a reinforced cuff formed as one piece on the one end.

3. A device in accordance with claim 2, wherein the connector is laterally formed as one piece on the reinforced cuff.

4. A device in accordance with claim 2, wherein the connector is separately manufactured and can be attached to the reinforced cuff.

5. A device in accordance with any one of the preceding claims, wherein a mixing element is located in the connector.

6. A device in accordance with any one of the preceding claims, wherein the sealing cannula tapers from one inner diameter towards the connector to a shorter inner diameter towards the one or more outlet openings.

7. A device in accordance with any one of the preceding claims, wherein the sealing cannula has inwardly oriented axially extending support ribs to provide said gap for conducting the fibrin sealant from the connector to the one or more outlet openings.

8. A device in accordance with claim 7, wherein the support ribs are arranged so that they extend at least substantially radially.

9. A device in accordance with any one of claims 2 to 8, wherein the working cannula is fixedly connected to a medical coupling which is maintained in the reinforced cuff of the sealing cannula in a frictionally and/or interlockingly sealing manner and extends axially with respect to the working cannula.

10. A device in accordance with any one of the preceding claims, wherein the sealing means comprises a radially inward directed annular sealing bead.

11. A device in accordance with any one of the preceding claims, wherein the sealing cannula is closed at the one end by means of a lead-in plug, in which a tube-shaped support envelope is sealed, which itself in turn extends through the entire sealing cannula and is sealed at the another end of the sealing cannula, and that the working cannula is guided freely movable in the support envelope, so that the fibrin sealant can flow in the gap between the supporting envelope and the sealing cannula from the connector as far as the one or more outlet openings.

12. A device in accordance with claim 11, wherein the support envelope is provided with a plurality of stiffening ribs which are directed radially outward and directed toward an inner wall of the sealing cannula.

13. A device in accordance with any one of the preceding

claims, wherein the sealing cannula has an abruptly widening rounded head at its another end where the working cannula emerges from the sealing cannula.

14. A device in accordance with claim 13, wherein the head has a axially extending annular sealing lip seated on the working cannula.

15. A device in accordance with any one of the preceding claims wherein each of the one or more outlet openings comprises a longitudinally extending slit.

16. A device substantially as hereinbefore described with reference to one or more of figures 1 to 5 or 6 to 10 of the accompanying drawings.

DATED this 29th day of November 1996

WHITE SPOT AG
By their Patent Attorneys
GRIFFITH HACK

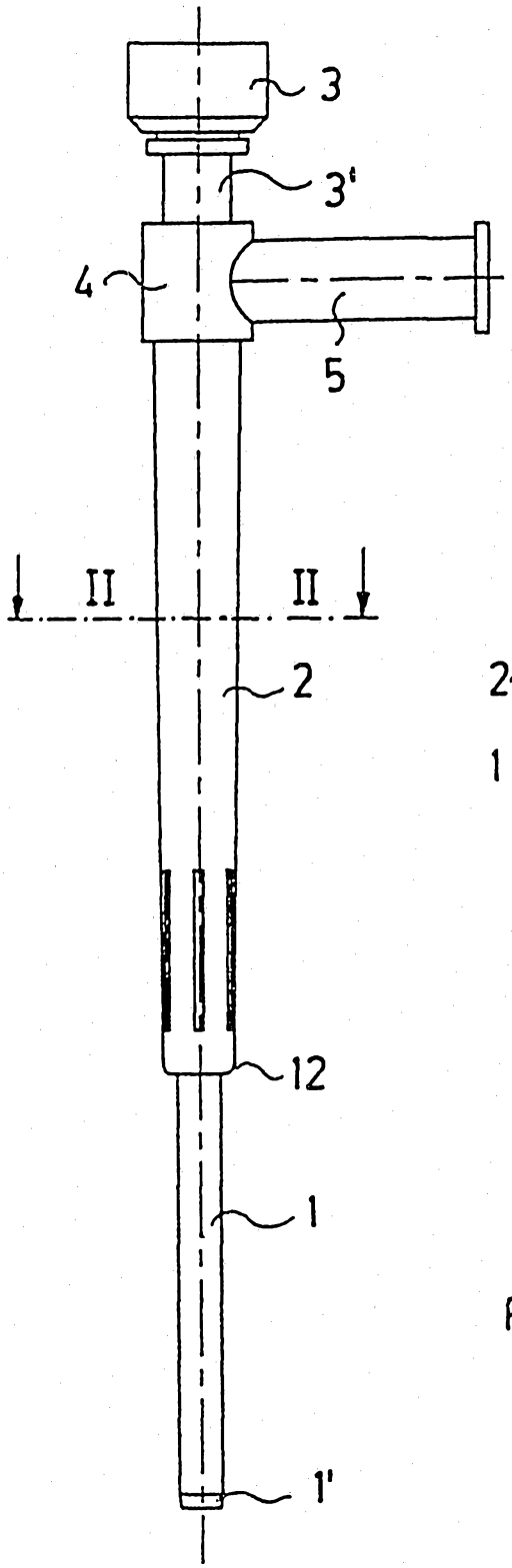
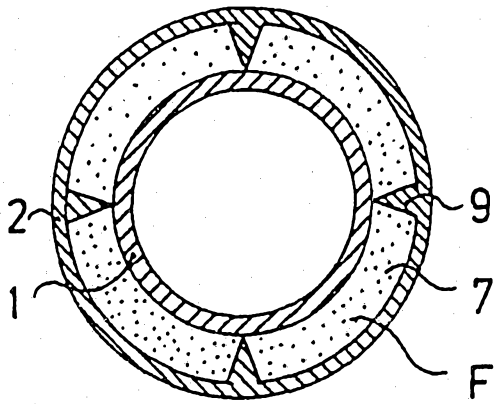


FIG. 1

FIG. 2



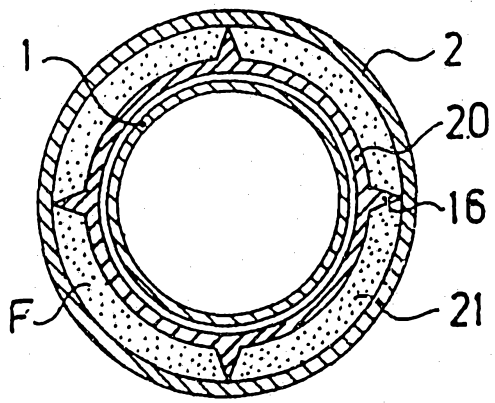


FIG. 7

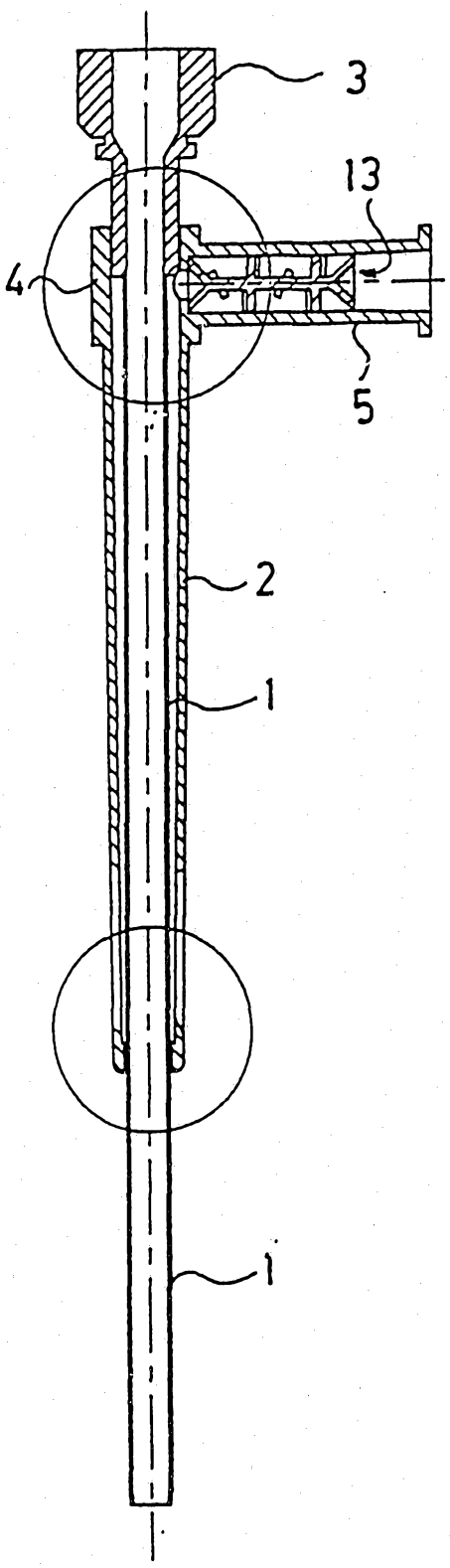


FIG. 3

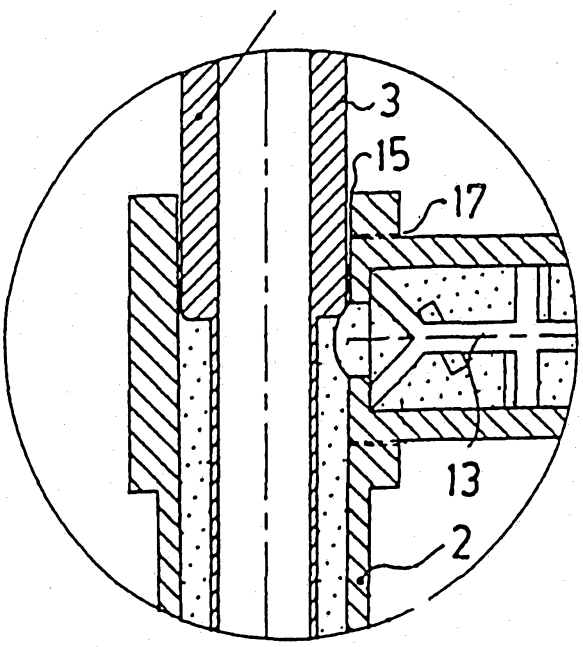


FIG. 4

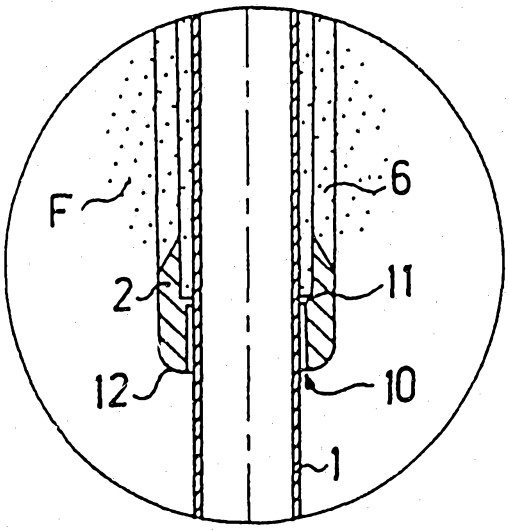


FIG. 5

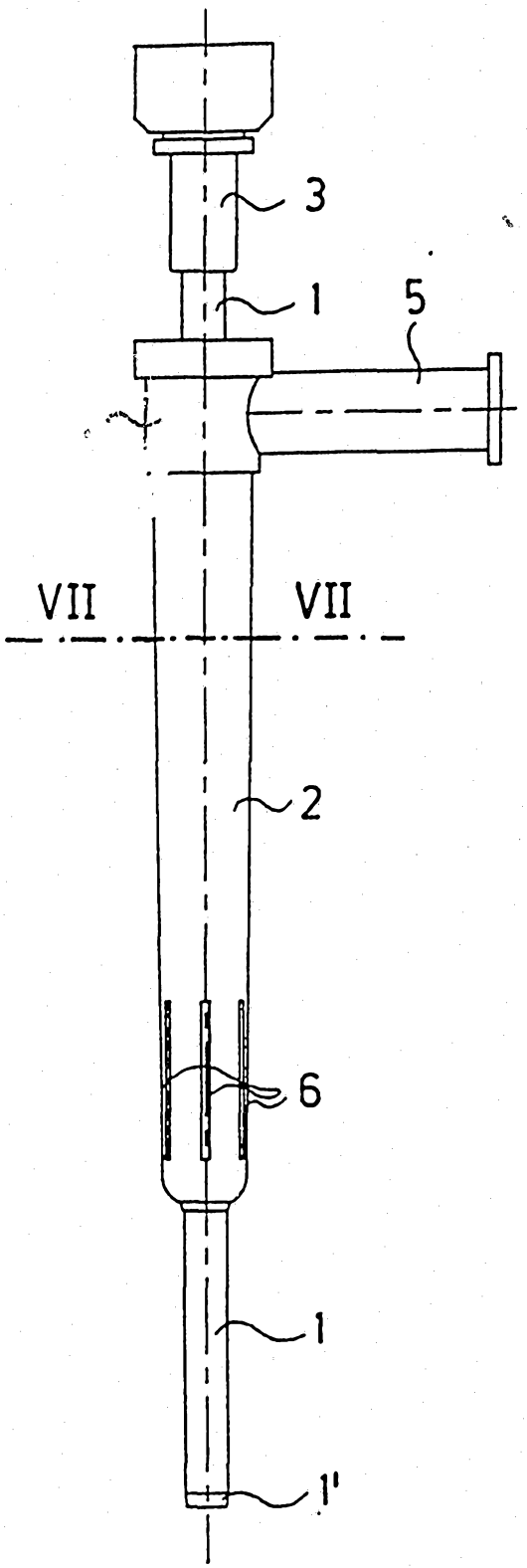


FIG. 6

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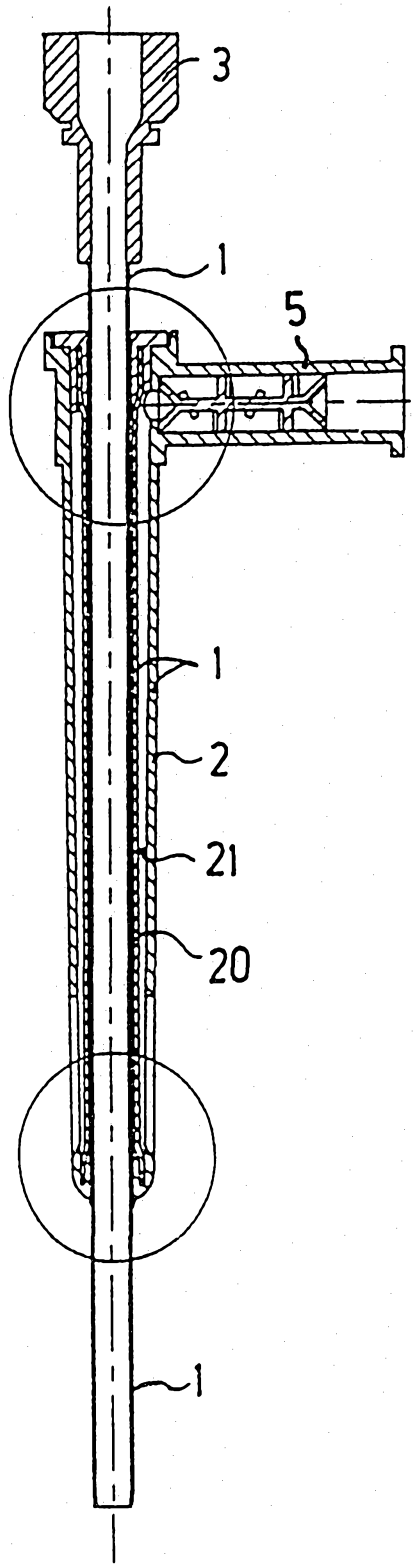

FIG. 8

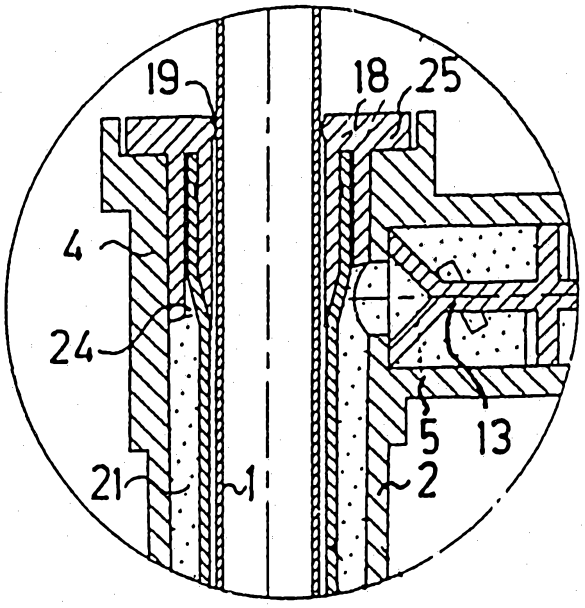

FIG. 9

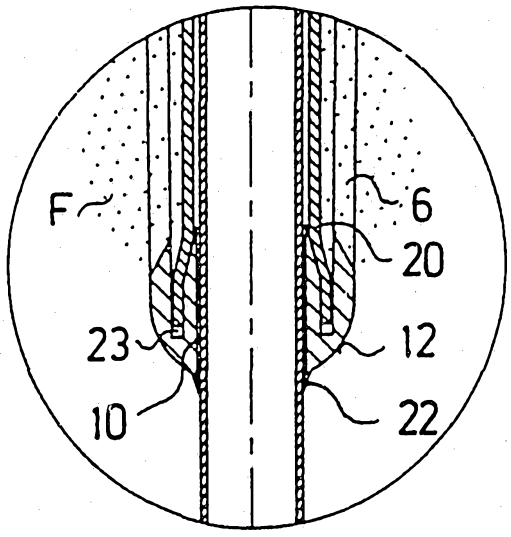

FIG. 10

INTERNATIONAL SEARCH REPORT

Interna l Application No
PCT/CH 94/00114

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61B17/00

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 5 A61B 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP,A,0 482 350 (DATASCOPE) 29 April 1992 see claims 1,16,17,19,20; figures	2-4,11,17
Y	FR,A,2 378 528 (TERSTEEGEN) 25 August 1978 see the whole document	2-4,11,17 13
A	US,A,1 882 213 (DONOVAN) 11 October 1932 see figure 3	6
A	EP,A,0 443 256 (URCAN MEDICAL) 28 August 1991 see column 6, line 9-15; figure 4	9,10,14
A	EP,A,0 241 038 (TERUMO) 14 October 1987	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in 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
22 July 1994	18.08.94
Name and mailing address of the ISA 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	Authorized officer Steenbakker, J

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CH 94/00114

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 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. [X] Claims Nos.: Claim 1
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1 (iv) PCT

2. [ ] Claims Nos.:
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:

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 II Observations where unity of invention is lacking (Continuation of Item 2 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.

INTERNATIONAL SEARCH REPORT

...rmation on patent family members

Interna l Application No
PCT/CH 94/00114

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A-0482350	29-04-92	EP-A-	0476178	25-03-92
		AU-A-	8384791	26-03-92
		CA-A-	2051360	22-03-92
FR-A-2378528	25-08-78	DE-A-	2703087	27-07-78
		CA-A-	1111733	03-11-81
		GB-A-	1572420	30-07-80
		JP-A-	53093686	16-08-78
		US-A-	4202332	13-05-80
US-A-1882213		NONE		
EP-A-0443256	28-08-91	US-A-	5209719	11-05-93
EP-A-0241038	14-10-87	JP-B-	5022551	29-03-93
		JP-A-	62236560	16-10-87
		US-A-	4832688	23-05-89

INTERNATIONALER RECHERCHENBERICHT

Interna' 'es Aktenzeichen
PCT/CH 94/00114

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 5 A61B17/00

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
IPK 5 A61B A61M

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
Y	EP,A,0 482 350 (DATASCOPE) 29. April 1992 siehe Ansprüche 1,16,17,19,20; Abbildungen	2-4,11,17
Y	FR,A,2 378 528 (TERSTEEGEN) 25. August 1978	2-4,11,17
A	siehe das ganze Dokument	13
A	US,A,1 882 213 (DONOVAN) 11. Oktober 1932 siehe Abbildung 3	6
A	EP,A,0 443 256 (URCAN MEDICAL) 28. August 1991 siehe Spalte 6, Zeile 9-15; Abbildung 4	9,10,14
A	EP,A,0 241 038 (TERUMO) 14. Oktober 1987	

☐ Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

☒ Siehe Anhang Patentfamilie

* Besondere Kategorien von angegebenen Veröffentlichungen :
"A" Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist
"E" älteres Dokument, das jedoch erst am oder nach dem internationalen Anmeldedatum veröffentlicht worden ist
"L" Veröffentlichung, die geeignet ist, einen Prioritätsanspruch zweifelhaft erscheinen zu lassen, oder durch die das Veröffentlichungsdatum einer anderen im Recherchenbericht genannten Veröffentlichung belegt werden soll oder die aus einem anderen besonderen Grund angegeben ist (wie ausgeführt)
"O" Veröffentlichung, die sich auf eine mündliche Offenbarung, eine Benutzung, eine Ausstellung oder andere Maßnahmen bezieht
"P" Veröffentlichung, die vor dem internationalen Anmeldedatum, aber nach dem beanspruchten Prioritätsdatum veröffentlicht worden ist
"T" Spätere Veröffentlichung, die nach dem internationalen Anmeldedatum oder dem Prioritätsdatum veröffentlicht worden ist und mit der Anmeldung nicht kollidiert, sondern nur zumVerständnis des der Erfindung zugrundeliegenden Prinzips oder der ihr zugrundeliegenden Theorie angegeben ist
"X" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann allein aufgrund dieser Veröffentlichung nicht als neu oder auf erfinderischer Tätigkeit beruhend betrachtet werden
"Y" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann nicht als auf erfinderischer Tätigkeit beruhend betrachtet werden, wenn die Veröffentlichung mit einer oder mehreren anderen Veröffentlichungen dieser Kategorie in Verbindung gebracht wird und diese Verbindung für einen Fachmann naheliegend ist
"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

1

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
22. Juli 1994	18. 08. 94
Name und Postanschrift der Internationale Recherchenbehörde Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Bevollmächtigter Bediensteter Steenbakker, J

Formblatt PCT/ISA/210 (Blatt 2) (Juli 1992)

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/CH94/00114

Feld I Bemerkungen zu den Ansprüchen, die sich als nicht recherchierbar erwiesen haben (Fortsetzung von Punkt 1 auf Blatt 1)

Gemäß Artikel 17(2)a) wurde aus folgenden Gründen für bestimmte Ansprüche kein Recherchenbericht erstellt:

1. [X] Ansprüche Nr. PATENTANSPRUCH 1
weil Sie sich auf Gegenstände beziehen, zu deren Recherche die Behörde nicht verpflichtet ist, nämlich
REGEL 39.1 (iv) PCT

2. [ ] Ansprüche Nr.
weil sie sich auf Teile der internationalen Anmeldung beziehen, die den vorgeschriebenen Anforderungen so wenig entsprechen, daß eine sinnvolle internationale Recherche nicht durchgeführt werden kann, nämlich

3. [ ] Ansprüche Nr.
weil es sich dabei um abhängige Ansprüche handelt, die nicht entsprechend Satz 2 und 3 der Regel 6.4 a) abgefaßt sind.

Feld II Bemerkungen bei mangelnder Einheitlichkeit der Erfindung (Fortsetzung von Punkt 2 auf Blatt 1)

Die internationale Recherchenbehörde hat festgestellt, daß diese internationale Anmeldung mehrere Erfindungen enthält:

1. [ ] Da der Anmelder alle erforderlichen zusätzlichen Recherchengebühren rechtzeitig entrichtet hat, erstreckt sich dieser internationale Recherchenbericht auf alle recherchierbaren Ansprüche der internationalen Anmeldung.

2. [ ] Da für alle recherchierbaren Ansprüche die Recherche ohne einen Arbeitsaufwand durchgeführt werden konnte, der eine zusätzliche Recherchengebühr gerechtfertigt hätte, hat die Internationale Recherchenbehörde nicht zur Zahlung einer solchen Gebühr aufgefordert.

3. [ ] Da der Anmelder nur einige der erforderlichen zusätzlichen Recherchengebühren rechtzeitig entrichtet hat, erstreckt sich dieser internationale Recherchenbericht nur auf die Ansprüche der internationalen Anmeldung, für die Gebühren entrichtet worden sind, nämlich auf die Ansprüche Nr.

4. [ ] Der Anmelder hat die erforderlichen zusätzlichen Recherchengebühren nicht rechtzeitig entrichtet. Der internationale Recherchenbericht beschränkt sich daher auf die in den Ansprüchen zuerst erwähnte Erfindung; diese ist in folgenden Ansprüchen erfaßt:

Bemerkungen hinsichtlich eines Widerspruchs

[ ] Die zusätzlichen Gebühren wurden vom Anmelder unter Widerspruch gezahlt.

[ ] Die Zahlung zusätzlicher Gebühren erfolgte ohne Widerspruch.

INTERNATIONALER RECHERCHENBERICHT
Angaben zu Veröffentlichungen die zur selben Patentfamilie gehören

Internat. Aktenzeichen
PCT/CH 94/00114

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie		Datum der Veröffentlichung
EP-A-0482350	29-04-92	EP-A-	0476178	25-03-92
		AU-A-	8384791	26-03-92
		CA-A-	2051360	22-03-92
FR-A-2378528	25-08-78	DE-A-	2703087	27-07-78
		CA-A-	1111733	03-11-81
		GB-A-	1572420	30-07-80
		JP-A-	53093686	16-08-78
		US-A-	4202332	13-05-80
US-A-1882213		KEINE		
EP-A-0443256	28-08-91	US-A-	5209719	11-05-93
EP-A-0241038	14-10-87	JP-B-	5022551	29-03-93
		JP-A-	62236560	16-10-87
		US-A-	4832688	23-05-89