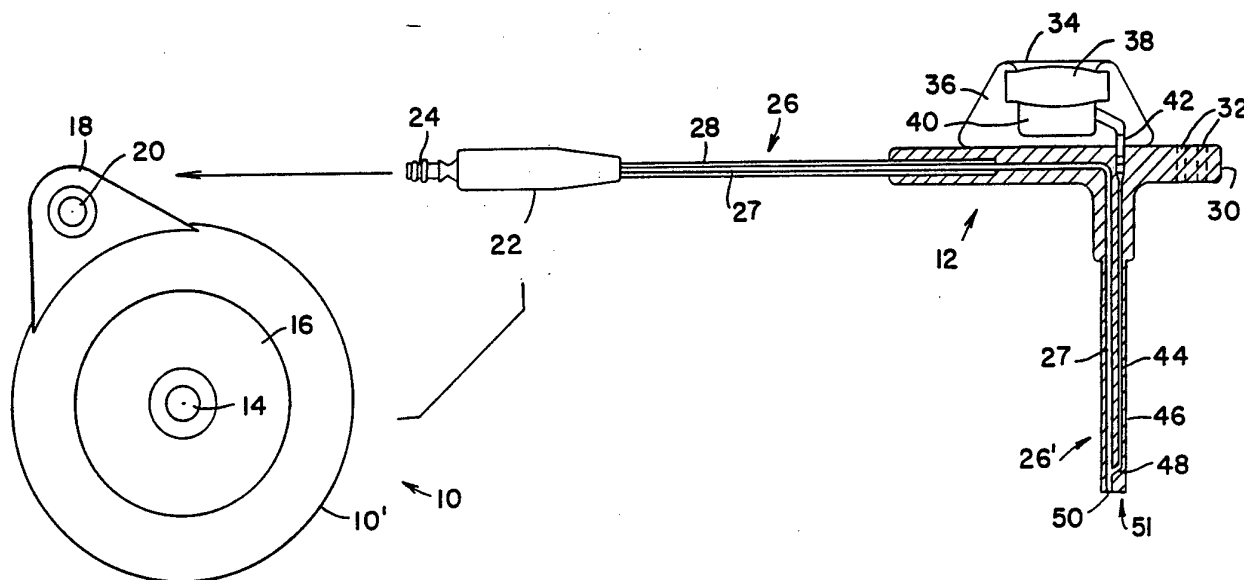




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(54) Title: DUAL ACCESS CATHETER FOR IMPLANTABLE PUMP SYSTEM



(57) Abstract

An implantable subsystem (10, 12) using a dual lumen catheter (26') having lumens (27, 44) joined near the distal end (51) to form a single outlet (50). The lumens may be of the same or unequal cross sections. The catheter may be formed in a rigid member (30) having a port body (36) attached to it or integrally formed. The catheter (26') has a first inlet being outlet (42) from cavity (40) of port body (36). The catheter has a second inlet being the output from an implantable pump (10').

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5 DUAL ACCESS CATHETER FOR IMPLANTABLE PUMP SYSTEM

Background of the Invention

This invention relates to implantable devices and, in particular, infusion systems. Specifically, it is directed to a catheter system which is used to provide access to a remote site within a body for purposes of infusion of medication, analysis of operation
10 of implantable systems, flushing an implantable device and removal of drug residing therein.

Drug infusion systems have been developed in which a pump is implanted in the body for purposes of dispensing metered doses of medication to a selected infusion site. Typically, the pump chamber can be refilled with infusate without the
15 necessity of removing the pump itself. This is done by injecting additional material transcutaneously through a septum located in the pump. Such pumps which are used to dispense medication at a relatively constant flow rate are represented by U.S. Patents 3,731,681 and 4,193,397. The devices have been commercialized as INFUSAID Models 100 and 400.

20 Implantable infusion systems also employ dual pumping chambers. This permits the system to dispense different infusate concentrations or even totally different medications to the same or to different infusion sites within the body. While a common system, they, in essence, act as two independent pumps each having its own pumping chamber which can be purged and refilled independently of the other. Representative
25 of this type of pump is U.S. Patent 4,258,711.

Yet another known implantable infusate system employs a single pumping chamber and a direct injection port, which is incorporated as a component of the pump. This port is essentially a chamber having an outlet conduit leading to an infusion site in the patient's body and an inlet port closed by a needle-penetrable
30 septum located underneath the patient's skin, which is accessible by transcutaneous injection.

In this type of device, a constant flow of infusate is obtained by means of the pump. If a bolus or supplemental dose is required such is administered by percutaneous injection into the port. Such a device can be used for ancillary purposes,
35 such as blood withdrawal, can be subjected to sophisticated analysis external to the pump itself to determine overall operation of the system. Representative of such a

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device is U.S. Patent 4,496,343. It employs a single catheter with the sideport T-ed into the pump outlet.

A system which employs a pump and side port combination for diagnostic purposes is found in U.S. Patent 5,006,997. By using the existing implanted hardware
5 coupled to external diagnostic equipment the working condition of the pump and catheter can be ascertained.

In some instances, a patient's drug protocol may call for the injection of two different drugs over a long period of time. A plurality of ports may therefore be implanted so that one particular drug can be supplied to two different sites within the
10 body, or that different drugs can be routed to the same infusion site without contamination.

Consequently, within the art a number of proposals exist that use catheters having a plurality of lumens. Two alternatives are illustrated in U.S. Patent 4,931,050, in particular, in Figs. 4B and 4C thereof. As illustrated therein, one alternative is an
15 ancillary port coupled to one lumen of a catheter with the other lumen coupled to the pump. Thus, two parallel drug infusion routes exist using a common catheter having two lumens. A variation is illustrated in Fig. 4C wherein two ports are used, one providing direct access to a lumen of the catheter while the other is T-ed to the pump and to the second independent lumen.

20 Multiple port arrangements having parallel catheter devices are illustrated, for example, in U.S. Patents 4,673,394, 4,692,146, 4,710,174 and 4,892,518. The lumens in some cases are separated by a common wall within a single tube, two distinct tubes, or two parallel tube elements encased in a single catheter housing. For example, the '394 patent employs a pair of ports each with its own outlet catheter. The catheters in
25 the '174 patent are separated from each other.

For example, a figure eight (8) double lumen catheter is disclosed in U.S. Patent 4,405,313. Such a catheter is a side by side system with two tubes attached together to provide multi purpose venous access such that blood products and medication can be simultaneously applied. The two lumens are connected and bridged by a smoothly
30 tapered filler so that a unitary catheter is defined even though the lumens may have unequal diameters. Thus, a single catheter body has two lumens.

Other multiple lumen systems are disclosed in U.S. Patents 4,639,246 and 4,955,861. For example, in the '861 patent a tapered concentric system is disclosed

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which allows multiple delivery simultaneously into an implantable pump having two different reservoirs.

While these prior art systems offer various advantages in terms of multiple drug delivery to the same or different sites and the ability to perform various diagnostic tests,
5 none provide direct port access to the catheter tip as well as the side port catheter.

Summary of the Invention

It is an object of this invention to provide a catheter configuration which provides clinical flexibility for operations employing implantable pumps.

Another object of this invention is to provide for a catheter configuration which
10 allows tip patency to be evaluated without the necessity of a drug being infused into the patient.

Yet another object of this invention is to provide a catheter system wherein blockage at the tip can be flushed without drug infusion into the patient. It is also desirable to have a system which allows the withdrawal of blood samples without the
15 risk of blockage in either the sideport or along the catheter lumen exiting from the sideport. Thus, an object of this invention is to provide a catheter system which permits withdrawal of fluids from the body without adversely effecting overall operation of the pump system.

These and other objects of this invention are accomplished by means of a dual
20 access catheter system which employs a double lumen catheter with the two lumens joined together proximal to the tip to form a short single lumen at the distal end. The catheter may be formed as an integral unit having the lumens therein and provided with various flange elements for purposes of anchoring the unit. It may also be formed with an integral port or, have a surface upon which the port is mounted with an outlet
25 thereof and fluid communication with one of the lumens. The lumens may have the same or different internal diameters. If needed, a liner for one of the lumens may also be employed.

This invention will be described in greater detail by referring to the attached drawing and the description of the preferred embodiment which follows.

30

Brief Description of the Drawing

Fig. 1 is a schematic view of a dual access catheter system in accordance with this invention; and

Fig. 2 is an enlarged schematic cut away showing the distal end of the dual lumen catheter.

Description of the Preferred Embodiment

Referring now to Fig. 1, the essential system components of this invention are depicted. The two major components are the pump subsystem 10 and the catheter subsystem 12. The pump subsystem 10 may be any commercially available infusion system, such as the INFUSAID Model 400, which employs a side port. The pump may be constant flow device or any flow metering or other pumping system, such as a programmable valve system, as illustrated in U.S. Patent 4,838,887.

Typically, such systems have a pump 10' a refill septum 14 and a drug reservoir, schematically illustrated as element 16. Not illustrated in Fig. 1 is the outlet from the drug reservoir 16 to an infusion site. Such devices also employ a sideport 18 having a septum 20 and an outlet catheter. A connector, typically a pump catheter connector 22, couples both the reservoir 16 and the side port 20 to the infusion site.

The catheter connector has a positive coupling plug connector 24 to establish a lockable connection between the catheter and the pump. It will be understood that this assembly can, of course, be disconnected to allow ancillary or replacement components to be attached to the pump subsystem 10. The catheter subsystem 12, in a first portion, comprises a catheter body (26) having a bore or lumen 27 and a liner, typically polyethylene 28.

In accordance with this invention, the catheter 26 is joined to the dual access catheter subsystem 12. The catheter subsystem 12, in a second portion, comprises a dual lumen catheter 26'. A rigid support member or flange 30 provides a support for a flange having suture holes 32. It will be understood that the number of suture holes and their placement vary as a function of size and application of this device. Also, the flange can be made to any conformal shape. Mounted on the support 30 is a tip access port 34. The access port 34 has a body member 36, a penetrable septum 38 and a small cavity 40. The outlet of the cavity 40 is in the form of a conduit 42 coupled to a bore or lumen 44. Lumen 44 and the catheter 26' may be housed in a rigid body 46. The rigid body 46 is integral with the support 30 in this embodiment. However, it may be made as separate elements.

The lumen 44 terminates near the distal end by convergence and merges with lumen 27 within catheter 26'. This is illustrated schematically as a bend or convergence

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zone 48. It will be appreciated that other geometries may be utilized to achieve convergence of the two lumens. The distal end 51 thus terminates in a single catheter tip or outlet 50. If necessary, the catheter may be extended by means of a short flexible tube.

5 Also, while illustrated as a unitary rigid element, it is apparent that the dual lumen catheter extension may be flexible itself and formed, for example, out of silicon attached in a convenient manner to the support 30.

Figure 2 shows such a flexible system. The catheter 26' having body 52 may be made of a flexible material, such as a silicone rubber or the like. The lumen coupled
10 to the side port 18 may be coated with a liner 28' such as polyethylene. Such a liner can be used if the system is using particular fluids. It may have an inside diameter greater than that of the lumen 44, which is in fluid communication with the tip access port 34. The cross-sectional configuration is a function of operational mode although different cross-sections add a degree of safety to the device. The bend or convergence
15 zone 48 is illustrated proximal to the tip or outlet 50.

In operation, the system provides an additional level of versatility for the clinician. Operation for purposes of dispensing infusate from the pump 10' through the catheter is unaffected. Likewise, bolus injections from the side port 18 are conducted as in a conventional system. However, utilizing the tip access port 34 in combination
20 with the dual lumen catheter a number of additional advantages occur.

First, tip patency at the outlet 50 can be evaluated without a drug being infused into the system. Using techniques, as disclosed in U.S. Patent 5,006,997, dealing with a pump diagnostic device (PDD), tip patency can be assessed utilizing the tip access port 34. It will be appreciated that utilizing those same techniques the catheter 26
25 exiting the pump sideport 18 can be evaluated for patency utilizing the sideport itself. This system thus permits a determination of patency at the tip. Such is important because that is a source of blockage in many applications.

A drug which resides in the catheter 26 exiting the side port 18 can be removed without infusing drug into the patient. This can be done utilizing both the side port 18
30 and the tip access port 34. By attaching a drain line to the sideport and an infusion line to the tip access port, the drug can be removed from the catheter without bodily fluids entering the catheter. That is, a flushing fluid is introduced via the lumen 44.

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Since a drain line is attached to the side port, a pressure differential exists in the two lumens with the lower pressure in the catheter 26. A fluid communication loop is thus established without bodily fluid entering the catheter tip 50.

Another important advantage is that blockage at the catheter tip 50 can be
5 flushed via the tip access port 34 without drug infusion into the patient. This is done by direct flushing utilizing the lumen 44 which, as illustrated in Figs. 1 and 2, merges with the lumen 27 carrying the drug approximal to the tip 50.

A reverse application is the withdrawal of blood samples or any other bodily fluids utilizing the tip access port 34. This can be done utilizing the lumen 44 without
10 risking any blockages in the sideport 18 or along the catheter lumen exiting the sideport. By this technique the catheter 26 is maintained in a drug delivery mode.

The tip access port 34 can also be used itself as a sideport, that is, it can be employed for a bolus injection of a drug different from one existing in the pump reservoir without disturbing the drug and the catheter lumen exiting the sideport 18.

15 It will be recognized by one of working skill that the system defined by this invention requires a surgical implant procedure that has associated with it additional steps. Thus, in addition to implanting the pump subassembly and the catheter, the tip access port 34 also requires implantation. The patient is thus provided with three distinct needle access sites. This may offer a degree of inconvenience to the patient
20 but provides, as explained herein, a much higher degree of flexibility to the clinician. Additionally, because the catheter has two discreet lumens it would have a slightly larger effective size. However, the inconveniences of implantation, are more than overcome by the advantages of this system.

One of the key advantages is used in an application involving insulin. As will
25 be appreciated, the infusion of insulin requires special handling given the nature of that material. Moreover, given the nature of the disease and the propensity for hypoglycemia during various procedures, this invention offers some unique advantages. For example, catheter tip evaluations can be performed without the risk of hypoglycemia by utilizing the PDD techniques directed to the tip access port 34. This
30 greatly shortens the procedure because the patient will not have to be monitored for a protracted length of time, for example, 4 hours as is the current regime. Importantly, the procedure does not involve any infusion of insulin, which is especially important for a brittle diabetic.

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Insulin can be removed from the catheter lumen 27 attached to the sideport, as well as the side port lumen proximal to the catheter by utilizing the tip access port 34 and the sideport 18. In this application drainage would be at the sideport 18 and infusion would be at the tip access port 34.

- 5 For example, insulin removal is required prior to the alkaline flush during a magnet procedure. This procedure is one that employs a magnet placed over a pump having valves that open and close such as an Infusaid M1000 (see also U.S. Patent 4,838,887). The magnet holds both inlet and outlet valves open. An alkaline flush solution is loaded into the pump 10' and extracted via the sideport 18 through septum
- 10 20. The alkaline solution dissolves any precipitation within the pump flow path. Again, this insulin removal technique prevents hypoglycemia.

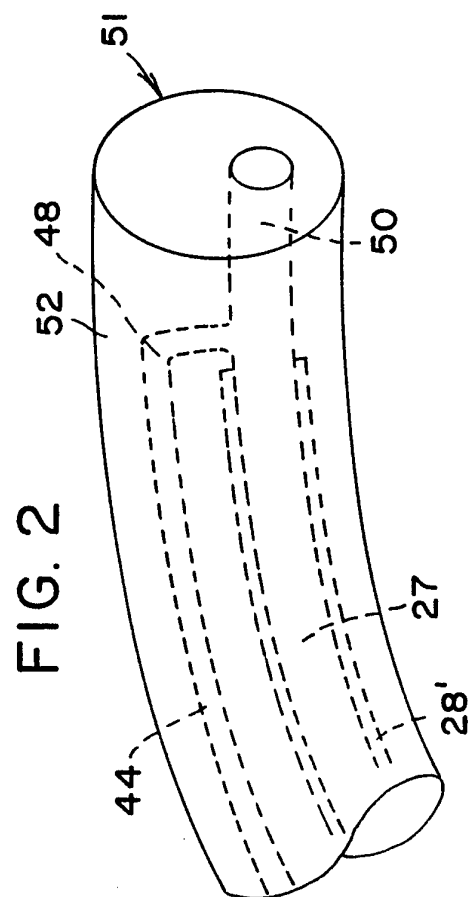
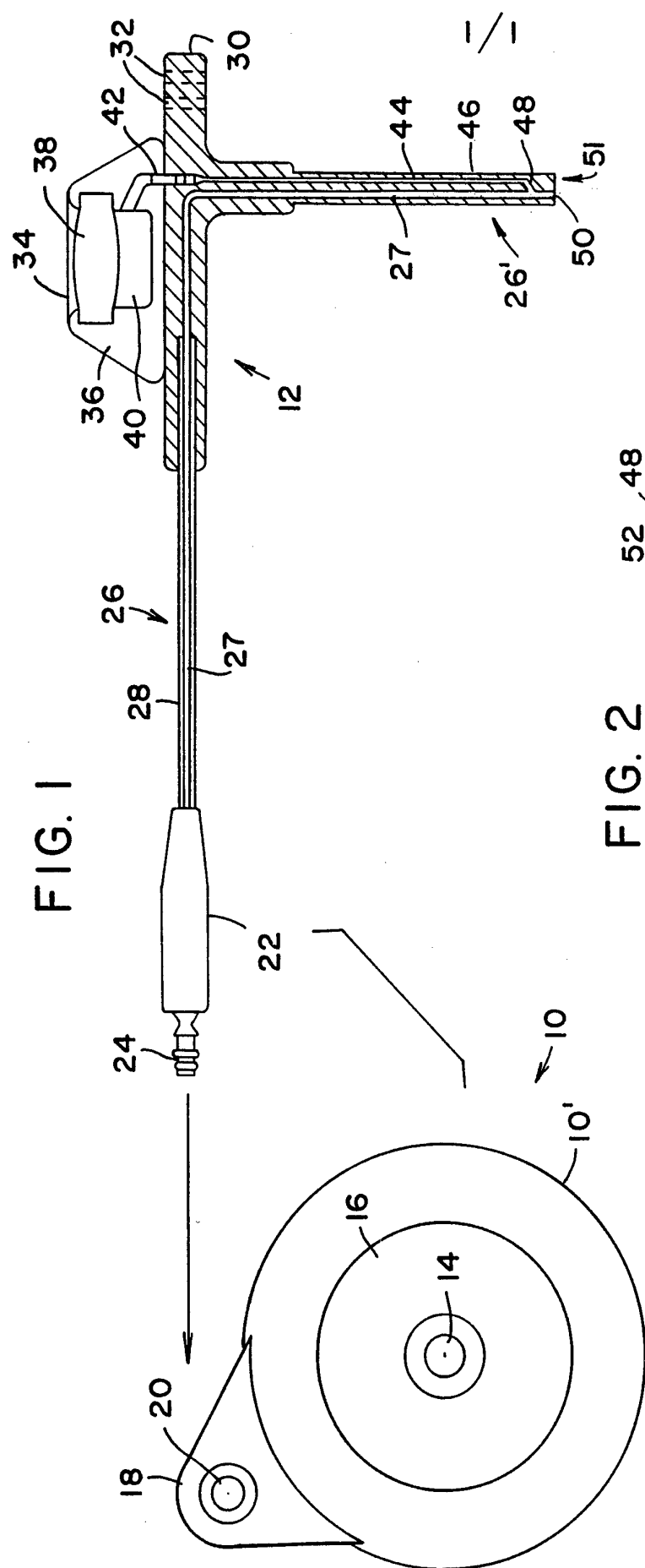
- Alkaline pump flushes can also be performed with increased safety. While utilizing the magnet to flush NaOH through the pump, the tip access port 34 can be used to infuse a diluent to the catheter tip 50. Thus, in the case of an accidental
- 15 NaOH infusion the diluent being infused into the tip access port 34 will deactivate the NaOH prior to exiting the catheter tip.

The system can also be used in an emergency mode. For a diabetic patient who is experiencing severe hypoglycemia during a procedure, the clinician can infuse dextrose directly into the tip access port to expedite rapid recovery.

- 20 It will be appreciated that modifications of this invention are within the purview and scope thereof.

CLAIMS

1. A catheter comprising:
a body having a distal end and at least two separate internal lumens,
means inside said body for coupling one lumen to be in fluid communication
5 with the other lumen, and
an outlet at said distal end for the other lumen.
2. The catheter of claim 1 wherein said body further comprises a support member having suture holes to anchor said body inside a bodily cavity.
3. The catheter of claim 1 further comprising a first access port to provide
10 a fluid input to one of said lumens and a second access port to provide fluid input to the other of said lumens.
4. The catheter of claim 1 wherein said means inside said body comprises a bend in said one lumen to join it to said other lumen.
5. The catheter of claim 4 wherein said bend of said one lumen is proximal
15 to said outlet.
6. The catheter of claim 1 wherein the cross sectional area of said one lumen is different from the cross sectional area of said other lumen.
7. The catheter of claim 1 further comprising an implantable pump, a connector for said other lumen to couple it in fluid communication to said implantable
20 pump, and a separate access port coupled in fluid communication to said one lumen.
8. The catheter of claim 7 further comprising means for coupling said body to living tissue and wherein said separate access and said means to couple said body are integral to each other and also contain said one lumen and said other lumen.
9. The catheter of claim 7 wherein said means inside said body comprises
25 a convergence zone proximate said distal end to join said one lumen and said other lumen.
10. The catheter of claim 9 further comprising a polyethylene liner extending in one of said lumens substantially to said convergence zone.



INTERNATIONAL SEARCH REPORT

PCT/US 93/02813

International Application No

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 A61M25/00; A61M39/02		
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 ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
P,X	EP,A,0 515 119 (SCIMED LIFE SYSTEMS, INC.) 25 November 1992 see page 2, line 1 - line 3 see page 3, line 18 - line 40 see page 8, line 34 - line 49 see figures 1,2,5-9,17	1,3-6
A	---	9
X	DE,A,3 713 061 (SIEMENS AG) 5 November 1987 see column 2, line 7 - line 15 see column 3, line 67 - column 4, line 15 see column 4, line 36 - line 41 see figure 2 ---	1,3-7
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¹⁰ 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 "I" 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 "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		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
24 JUNE 1993	27.07.93	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	SCHOENLEBEN J.	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
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**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

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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
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