United States District Court,
N.D. Illinois, Eastern Division.

Sakharam D. MAHURKAR, M.D. and Sherwood Medical Company d/b/a Kendall/Sherwood-Davis & Geck,
Plaintiffs.
v.
ARROW INTERNATIONAL, INC,
Defendant.

Aug. 9, 2001.

Owner of patents for dual-lumen catheter and catheter assembly sued competitor for infringement. Construing claim language, the District Court, Morton Denlow, United States Magistrate Judge, held that: (1) "relative concentration of material" extending from second opening, meant sufficient material to stiffen tip relative to remainder of catheter body; (2) catheter tip could be either centered cone or off-center cone; (3) "unitary tube" meant that tube and tip had to be single unit; and (4) disclosed structure corresponding to "connecting means" included Y-connector fastened to bent extension tubes and unitary connecting member.

Claims construed.

4,583,968, 4,895,561. Construed.

Kenneth J. Jurek, Rosanne J. Faraci, McDermott, Will & Emery, Chicago, IL, for Plaintiffs.

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MEMORANDUM OPINION AND ORDER

MORTON DENLOW**, United States Magistrate Judge.**

Plaintiffs, Dr. Sakharam D. Mahurkar ("Dr.Mahurkar"), owner of United States Patent No. 4,583,968 and Patent No. 4,895,561 and patent licensee, Sherwood Medical Company d/b/a Kendall/Sherwood-Davis & Geck ("Kendall") (collectively "Plaintiffs"), bring this patent infringement claim against Defendant Arrow International, Inc. ("Arrow"). A Markman hearing was held July 12, 2001 to construe the disputed claims of the 4,583,968 patent and the 4,895,561 patent. A detailed analysis of the Court's construction of the claims is set forth below.

I. BACKGROUND

A. TECHNICAL BACKGROUND

The patents-in-suit and the accused Arrow products all involve double-lumen catheters for use in hemodialysis. The role of kidneys in the body is to remove toxins from blood. When kidneys fail to function properly due to disease or injury, blood must be cleaned externally. In hemodialysis, blood is removed from a patient, diverted to a blood treatment unit where it is cleansed, and then returned to the patient. Hemodialysis catheters are devices that are inserted into a patient's vein for removal and return of blood. A double lumen hemodialysis catheter has two separate lumens, or channels, one for removing and one for returning blood. In re Mahurkar, 831 F.Supp. 1354 (N.D.Ill.1993) (Easterbrook, J. sitting by designation).

A typical hemodialysis blood treatment system includes a blood treatment unit for cleansing the blood, a catheter inserted into a patient's vein for removal of the uncleansed blood and return of cleansed blood, and various connectors and extension tubes that connect the catheter to the blood treatment unit. Patients with diseased or damaged kidneys generally return to a hospital or clinic for regular hemodialysis.

There are over 25,000 U.S. patents that contain the term "catheter" in their specifications and almost 5,000 U.S. patents with this term in their title. The patents-in-suit relate to a certain subset of catheters, double lumen catheters.

B. DR. MAHURKAR, THE INVENTOR

Dr. Mahurkar is a licensed nephrologist who has lived in Chicago for the past 29 years. Until his retirement in 1995, Dr. Mahurkar conducted research and taught nephrology and internal medicine at Cook County Hospital in Chicago. In addition, Dr. Mahurkar has been an inventor, receiving 28 U.S. patents, primarily dealing with catheters and syringes. He has also published a number of academic articles on hemodialysis.

In the 1970s, Dr. Mahurkar designed a catheter divided internally by a septum which created two equal "D" shaped or semi-circular lumens ("double D") and having a beveled tip. This catheter is the subject of Dr. Mahurkar's first patent, U.S. Patent No. 4,134,402 ("the '402 patent"), which expired in 1997 and is not asserted in this suit.

In the early 1980s, Dr. Mahurkar filed a series of patent applications covering variations to his original double D catheter design relating to the catheter tip, and the holes or ports on the catheter. These improvements resulted in two inventions: (1) smooth bore septum-type double lumen catheters; and (2) bent extension catheter assemblies. The patents protecting these two inventions, U.S. Patent No. 4,583,968 ("the '968 patent") and U.S. Patent No. 4,895,561 ("the '561 patent"), are the two patents involved in this litigation.

C. THE '968 PATENT**-SMOOTH BORE SEPTUM TYPE** DOUBLE LUMEN CATHETERS

The '968 patent, FN1 entitled "Smooth Bore Double Lumen Catheter," was issued to Dr. Mahurkar on April 22, 1986. The '968 patent is a catheter which is made of a cylindrical tube divided into two separate lumens. One lumen is used for removing unclean blood, and the other for returning cleansed blood. The exterior of the cylindrical tube is a smooth bore, and the tip of the tube is conical, making the catheter easy to insert.

FN1. A copy of the '968 patent is attached as Exhibit A to this opinion.

D. PRIOR LITIGATION BETWEEN THE PARTIES

The present suit is not the first litigation between Dr. Mahurkar and Arrow concerning the '968 patent. In 1991, Dr. Mahurkar sued Arrow for infringement of the '968 patent. On July 22, 1992, the parties entered into an agreed order which terminated the case. Pursuant to the order, Arrow agreed to stop selling catheters having double D designs.

In July 1998, Dr. Mahurkar filed a motion for contempt, in which Kendall intervened, alleging that Arrow's post-agreed order catheters violated the agreed order and infringed claim 19 of the '968 patent. Judge Andersen denied Dr. Mahurkar's motion holding that the issues raised should be the subject of a new lawsuit. This action follows that decision.

E. OTHER LITIGATION INVOLVING THE '968 PATENT

In 1990, Dr. Mahurkar and Quinton Instrument Company ("Quinton"), Dr. Mahurkar's then licensee, filed a lawsuit against IMPRA, Inc., a non-party to the pending litigation, alleging infringement of the '968 patent. The case went to trial against defendant IMPRA before Judge Easterbrook in the Northern District of Illinois. In re Mahurkar, 831 F.Supp. 1354 (N.D.Ill.1993), *aff'd,* 71 F.3d 1573 (Fed.Cir.1995).

Claims 1 and 19 of the '968 patent were at issue in the case. Judge Easterbrook found IMPRA infringed on Mahurkar's patent. Id. Judge Easterbrook's reasoning and conclusions are extremely useful for the Court in construing the claims presented in this case. The Court will address relevant portions of Judge Easterbrook's opinion.

F. THE '561 PATENT**-BENT EXTENSION CATHETER ASSEMBLIES**

The '561 patent, FN2 entitled "Dual-Lumen Catheter-Connecting System," was issued to Dr. Mahurkar on January 23, 1990. The '561 patent concerns the portion of the catheter assembly that connects the catheter tube to the blood treatment unit. This invention improves patient comfort for certain types of catheter placements, and reduces the likelihood the catheters will pull out of the vein during or between hemodialysis treatments.

FN2. A copy of the '561 patent is attached as Exhibit B to this opinion.

The present litigation involves two separate patent infringement suits that have been consolidated for discovery. The first suit, 98 C 4890, alleges infringement of the '561 patent, and the second suit, 99 C 5711, alleges infringement of the '968 patent. The parties have consented to this Court conducting the Markman hearing.

The Court will first explain the rules of claim construction and will then apply those rules to the disputed claims in the '968 patent and the '561 patent.

II. RULES OF CLAIM CONSTRUCTION

[1] An infringement analysis involves two steps. The first step is determining the meaning and scope of the patent claims allegedly infringed, also known as claim construction or interpretation. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995)(en banc) *aff'd* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Claim construction is a matter of law for decision by the courts. Id. at 970. The second step is comparing the properly construed claim to the instrument accused of infringing. Id. at 976. This proceeding

is concerned with the first step, commonly known as a Markman hearing.

A. SOURCES AND HIERARCHY FOR CLAIM INTERPRETATION

[2] [3] In interpreting a claim, a court first looks to the language of the claim, which defines the breadth and depth and bounds of the claim. York Products, Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed.Cir.1996). The general rule is that terms in the claim are to be given their ordinary and accustomed meaning. Johnson Worldwide Assoc., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed.Cir.1999). A court must presume that the terms of the claim mean what they say, and give full effect to the ordinary and accustomed meaning of the claim terms unless otherwise compelled. *Id*. There are two instances in which a court may be compelled to give the definition of a term a meaning outside of the ordinary and accustomed one. The first one arises when a patentee has chosen to be his own lexicographer, as long as the special definition of the term is clearly stated in the patent specification or file history. *Id*. at 990; Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). The second arises when the terms chosen by the patentee "so deprive the claim of clarity that there is no means by which the scope of the claim may be ascertained from the language used." Zebco, 175 F.3d at 990.

[4] Second, the court looks to the patent specification, containing a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it. Vitronics, 90 F.3d at 1582. It is here where, if the patentee chooses to be his own lexicographer, the special meanings of the claim terms are typically found. *Id*. The specification is "always highly relevant" and is usually dispositive; it is the "single best guide to the meaning" of a disputed term. *Id*. All claims must be read in view of the specification, which acts as a sort of dictionary to explain the invention and may define the terms used in the claim. Markman, 52 F.3d at 979.

[5] Third, the court may also consider the prosecution history of the patent, which contains the complete record of the proceedings before the Patent and Trademark Office ("PTO"), including any express representations made by the patentee regarding the scope of the claims. Vitronics, 90 F.3d at 1582. The prosecution history is often significant when determining the scope of a claim. *Id*. The prosecution history can and should be used to understand the language used in the claim, however, it can not be used to enlarge, diminish or vary the terms in the claim. Markman, 52 F.3d at 980. Included within an analysis of the file history may be an examination of the prior art cited therein, as the prior art gives guidance as to what the patent does and does not cover. Vitronics, 90 F.3d at 1583.

[6] Finally, extrinsic evidence consisting of expert and inventor testimony, dictionaries and learned treatises, may be considered only to assist in the court's understanding of the patent, not to vary or contradict the terms of the claims. Markman, 52 F.3d at 980-81. However, in most situations, an analysis of the intrinsic evidence alone resolves a disputed claim term and unambiguously describes the scope of the patented invention. Vitronics, 90 F.3d at 1583. Under these circumstances reliance on extrinsic evidence is improper. *Id*.

[7] [8] [9] In terms of hierarchy, evidence that is objective, reliable, and publicly accessible, such as prior art documents, dictionaries and treatises are preferred over other types of extrinsic evidence. *Id*. at 1585. Although dictionaries and treatises fall within the category of extrinsic evidence, they are worthy of special consideration. Judges are free to consult such resources at any time to better understand the underlying technology, and may rely on dictionary definitions as the ordinary and accustomed meaning of a term, as long as the dictionary definition does not contradict any definition found in or ascertained by a reading of

the patent. *Id*. at 1584 n. 6. Prior art, although also extrinsic evidence, may be included in an analysis of the prosecution history if cited therein. *Id*. at 1583. A court may rely on prior art proffered by one of the parties, even if not cited in the specifications and file history, to aid in the court's understanding and to demonstrate how a disputed term is used by those skilled in the art. *Id*. at 1584. Opinion testimony of experts and the inventor should be treated with "utmost caution" and may only be relied upon if the patent documents taken as a whole are insufficient to enable the court to construe disputed claim terms, which is rare, if ever. *Id*. at 1584-85.

B. PATENTS ARE GENERALLY UNAMBIGUOUS

In most situations, there is no "ambiguity" in the claim language. Markman, 52 F.3d at 986. Statutory language requirements are designed to avoid ambiguity in a patent. *Id*. The statute requires that the specification contain a written description in "full, clear, concise and exact terms." 35 U.S.C. s. 112. Patent applications are reviewed by examiners at the PTO who are "trained in the law and presumed to have some expertise in interpreting the prior art references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents." Markman, 52 F.3d at 986. Thus, "[i]f the patent's claims are sufficiently unambiguous for the PTO, there should exist no factual ambiguity when those same claims are later construed by a court of law in an infringement action." *Id*.

However, because "a judge is not usually a person conversant in the particular technical art involved and is not the hypothetical skilled in the art to whom a patent is addressed, extrinsic evidence may be necessary to inform the court about the language in which the patent is written. But this evidence is not for the purpose of clarifying ambiguity in claim terminology. It is not ambiguity in the document that creates the need for extrinsic evidence but rather unfamiliarity of the court with the terminology of the art to which the patent is addressed." *Id*.

C. LIMITATIONS NOT SET FORTH IN THE CLAIM MAY NOT BE READ INTO THE CLAIM

[10] [11] [12] There are two familiar claim construction canons regarding limitations imposed on claims, setting forth the relationship between the claims and the written description: 1) one may not read a limitation into a claim from the written description, and 2) one may look to the written description to define a term already in a claim limitation, as a claim must be read in view of the specifications of which it is a part. Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed.Cir.1998). Thus, a limitation must appear in the language of the claim before one looks to the written description to define that limitation. "This is so because the claims define the scope and the right to exclude, and the claim construction inquiry ... begins and ends in all cases with the actual words of the claim." *Id*.

[13] [14] Without a term in the claim that would direct us to the written description for clarification, there is no legitimate way to narrow the claim. *Id*. Similarly, if the written description provides us a definition of a term used in the claim, then reading in a further limiting definition would be improper. Mantech Environmental Corp. v. Hudson Environmental Serv. Inc., 152 F.3d 1368, 1374 (Fed.Cir.1998). The Supreme Court explained this requirement, stating, "We know of no principle of law which would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty of infringement. The difficulty is that if we once begin to include elements not mentioned in the claim in order to limit such claim...., we should never know where to stop." Renishaw, 158 F.3d at 1248 (quoting McCarty v. Lehigh Val R.R., 160 U.S. 110, 116, 16 S.Ct. 240, 40 L.Ed. 358 (1895)).

[15] [16] [17] [18] Words in a claim should be accorded their ordinary and accustomed meaning, not a

narrower scope than what is ordinarily accorded it. Renishaw, 158 F.3d at 1249. Thus, when a claim term contains a general descriptive term, the term will not be limited to a numerical range that is included in the written description. Similarly, a general term cannot be reduced to a narrower scope or subset of that term by a modifier if the claim does not expressly contain the modifier. For example, if the claim term recites a general noun without limiting that noun with an adjective, the claim should be construed to cover all known types of that general noun supported by the patent disclosure. Id. at 1250. Likewise, if the words of the claim recite a general verb without limiting it with an adverb, the claim should be construed to cover the ordinary broader meaning of the verb. *Id*.(citing Virginia Panel Corp. v. MAC Panel Co., 133 F.3d 860 (Fed.Cir.1997) (holding that "reciprocating" is not limited to linearly reciprocating)). In looking at the written description to define the scope of a claim term, the varied use of a term demonstrates the breadth of the term, demanding a broad construction, rather than a narrow one. Zebco, 175 F.3d at 991.

[19] However, a common meaning, such as one found in a dictionary, that is inapposite to the context of the patent disclosure is not one that the court should adopt. *Id*. Indiscriminate reliance on definitions found in dictionaries can produce absurd results if not read in light of, and in the context of, the patent specifications. *Id*.

D. THE SCOPE OF THE CLAIM IS NOT LIMITED TO THE PREFERRED EMBODIMENT

[20] As a general rule, the claim is not limited by the language of the preferred embodiments or specific examples included in the specification. Karlin Technology Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 972 (Fed.Cir.1999). "It is well settled that device claims are not limited to devices which operate precisely as the embodiments described in detail in the patent." *Id*. (quoting Virginia Panel, 133 F.3d at 866). Similarly, mere inferences drawn from the description of an embodiment cannot serve to limit claim terms. Johnson, 175 F.3d at 992. "Although the specification may aid the court in interpreting the meaning of disputed claim language,particular embodiments and examples in the specification will not generally be read into the claims." Comark Communications, Inc. v. Harris Corporation, 156 F.3d 1182, 1186 (Fed.Cir.1998). The law "does not require that an applicant describe in his specification every conceivable and possible future embodiment of his invention. The law ... requires only that the inventor describe the 'best mode' known at the time to him in making the invention." SRI International v. Matsushita Electric Corp. of America, 775 F.2d 1107, 1121(Fed.Cir.1985).

E. THE LITERAL SCOPE OF A MEANS-PLUS-FUNCTION CLAIM IS THE RECITED FUNCTION PERFORMED BY THE CORRESPONDING DISCLOSED STRUCTURE OR ITS EQUIVALENT STRUCTURES

[21] Pursuant to 35 U.S.C. s. 112, para. 6, a claim element "may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof." The claim elements written in this format are construed to cover the corresponding structures described in the specification, and equivalents thereof. *Id*.

[22] A court's task in construing a means-plus-function element involves two steps. First, the court identifies the function portion of the element and construes any disputed terms in the function language. Second, the court identifies the corresponding structure(s) disclosed in the specification linked or associated with that function. Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1308 (Fed.Cir.1998); B. Braun Medical, Inc. v. Abbott Lab., 124 F.3d 1419, 1424 (Fed.Cir.1997)(corresponding structure must be linked or associated with recited function). To determine the claimed function, the court must construe the specific terms in the claim. Chiuminatta Concrete Concepts, 145 F.3d at 1308. A means-plus function claim

is indefinite, and thus invalid, if the specification fails to disclose an adequate structure corresponding to the means limitation. Kemco Sales, Inc. v. Control Papers Co., 208 F.3d 1352, 1360-61 (Fed.Cir.2000).

[23] Not all aspects of the structure disclosed in the specification should be included in the court's claim construction. Details of the disclosed structure that are "unrelated to the recited function" are not "corresponding structure," and do not limit the scope of the means clause. Chiuminatta Concrete, 145 F.3d at 1308.

F. DIFFERENT CLAIMS IN A PATENT ARE PRESUMED TO HAVE A DIFFERENT SCOPE

[24] The doctrine of claim differentiation creates a presumption that different claims in a patent have a different scope. Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed.Cir.1998). The doctrine "is ultimately based on the common sense notion that different words or phrases used in separate claims have different meaning and scope." Karlin Technology, Inc.,. 177 F.3d at 971-72. For example, a limitation found in a dependent claim ordinarily should not be read into the independent claim from which it depends. Id. at 972; *See also* Whittaker Corp. v. UNR Indus., Inc., 911 F.2d 709, 712 (Fed.Cir.1990) ("it is inconsistent with the principle of claim differentiation that...an independent claim should be given the same meaning" as claims that depend from the independent claim).

III. CLAIM INTERPRETATION-THE '968 PATENT

[25] The elements of the '968 patent requiring construction by the Court are all found in Claims 12, 13, 14, 17, 18, 19 and 21-24. FN3

FN3. Some of the terms in the '968 patent requiring construction appear in multiple claims. Identical claim terms appearing in multiple claims of a patent, "must be construed consistently." Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1574 (Fed.Cir.1995). Therefore, the Court will only address each disputed term the first time it appears in the patent and the construction of the term will apply for each claim where the term is found.

A. CLAIM 12

Claim 12 reads as follows, with language to be construed in bold:

A double lumen catheter comprising an elongated cylindrical tube including a planar axial divider bisecting said cylindrical tube into first and second lumens, the proximal end of said cylindrical tube connecting two separate tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said cylindrical tube to a first opening at the distal end of said cylindrical tube, the second lumen extending from the proximal end of said cylindrical tube to a second opening in the side of the cylindrical surface of said cylindrical tube, said second lumen terminating at said second opening and **a relative concentration of material extending axially from the second opening to the distal end of said cylindrical tube,** the distal end of said cylindrical tube having **a smooth conical tapered tip** that smoothly merges with the cylindrical surface of said cylindrical tube, the cylindrical surface of said cylindrical tube having at least one side hole exposing said first lumen axially spaced between said second opening and said conical tapered tip and circumferentially disposed on the opposite side of said cylindrical tube as said second opening, and the cylindrical surface of said cylindrical tube having at least one side hole exposing said second lumen axially spaced between said second opening

and the proximal end of said cylindrical tube and circumferentially disposed on **the same side** of said cylindrical tube as said second opening.

1. Language in Dispute: "A relative concentration of material."

[26] FN4**Does "a relative concentration of material" mean (1) the presence of some material relative to the hollow lumens or (2) sufficient material to stiffen the tip relative to the remainder of the catheter body?**

FN4. For each issue to be decided by the Court, Plaintiffs' proposed claim interpretation is listed as (1) and Defendant's proposed claim interpretation is listed as (2).

Answer: "A relative concentration of material" means sufficient material to stiffen the tip relative to the remainder of the catheter body.

a). Claim Language

The Court must interpret the term "relative concentration of material." The term "relative" is a comparative term and requires a determination of what is being compared. The claim does not explain to what the relative concentration of material should be compared. Plaintiffs argue it should be compared to the hollow lumen. Arrow argues that when looking at the claim language in the patent, the meaning of "relative concentration of material" cannot be determined because it does not say to what it is relative. The Court agrees. Therefore, the Court must look to the specification and written descriptions for guidance.

b). Written Description

The specification of the '968 patent supports Arrow's construction of the claim. The specification clearly demonstrates that the term "relative" relates to a comparison of the stiffness or rigidity between the catheter tube, the body, and the tip. Each time the words "relative concentration of material" appear in the specification, they appear as a relative concentration to stiffen the tip. This is true in the Abstract, the Summary of the Invention, and also in the Preferred Embodiment.

The abstract explains: "to provide improved dilator characteristics, preferably the tip includes a relative concentration of material for rigidity." (Abstract). Similarly, the summary of the invention describes the conical tapered tip: "[it] comprises a relative concentration of material to impart relative rigidity so that the tip functions as an effective dilator for soft tissue and veins." ('968 patent, col. 2, lines 38-41). In the preferred embodiment, the specification describes figure 7 as showing a conical tip formed with "a relative concentration of material 23 to stiffen the tip 20. This stiffening aids penetration of the tip 20 into the body cavity (not shown) and also aids the dilation of soft tissue such as veins." ('968 patent, col. 4, lines 16-21).

c). Prosecution History

The prosecution history is also consistent with Arrow's claim construction. Dr. Mahurkar described the purpose of the relative concentration of material in his prosecution of the '968 patent: "This relative concentration of material further prevents kinking of the catheter tip during insertion." (Def. Ex. 2 at NSHN 128717). Thus, it is the relative concentration of material that stiffens the tip relative to the catheter body, which prevents it from kinking.

d). Prior Litigation

Judge Easterbrook in his opinion In re Mahurkar, 831 F.Supp. 1354, 1359 (N.D.Ill.1993) discussed figure 7 of the '968 patent. He explained that figure 7 "shows that the intake lumen of the Mahurkar catheter is sealed off below the intake ports and replaced with a plug of plastic, which the claims of the patent call a 'relative concentration of material.' (This both stiffens the tip and eliminates space in which blood may pool and clot.)" In re Mahurkar, 831 F.Supp. at 1359.

2. Language in Dispute: "Extending Axially."

[27] **Does material "extending axially from the second opening to the distal end of said cylindrical tube" mean (1) material present in the second lumen between the inlet opening and the tip or (2) material to run continuously from the inlet opening through the tip?**

Answer: Material "extending axially from the second opening to the distal end of said cylindrical tube" means material to run continuously from the inlet opening through the tip.

a). Claim Language

The issue in construing this language is whether the material must run continuously from the inlet opening through the tip. Dr. Mahurkar argues the term "extends axially" means that the material extends, or reaches toward the base of the conical tip from the inlet opening, but does not have to be continuous.

Arrow argues the claim language requires the relative concentration of material extend continuously from the second opening to the distal end of the cylindrical tube which has a conical tip. Therefore, the distal end includes the tip and the language extending axially from the second opening to the distal end requires there to be continuous material throughout.Thus, in order for the material to go from the opening through to the tip axially, in that direction, it must go continuously.

The Court holds the claim limitation requires the relative concentration of material to go continuously from the inlet opening to the tip. The use of the term "extends axially" describes both the direction and the fact that it is continuous in that direction. To extend means to straighten out or to stretch out to full length. (Webster's II New Riverside University Dictionary 456 (1994)).

b). Written Description

Figure 7 is the only illustration in the patent of the "relative concentration of material." Arrow argues this figure is consistent with its construction of claim 12 because it depicts a solid material which runs continuously from the opening of the inlet through the tip.

The specification regarding figure 7 says, "As shown in fig. 7, the inlet lumen 14 terminates at the inlet aperture 19 and in place of the inlet lumen the relative concentration of material extends axially from the aperture to the distal end of the tube at the truncated apex of the conical tip." ('968 patent, col. 4, lines 21-25). The parties agree the specification calls for the relative concentration of material to be continuous, however Dr. Mahurkar argues this is one embodiment, and is not a requirement. The Court holds the written description accurately describes the claim.

c). Prior Litigation

In the earlier litigation, Judge Easterbrook stated that "extending axially" means " a relative concentration 'extending' from intake through outlet." In re Mahurkar, 831 F.Supp. at 1382. To demonstrate what the court meant by "extending axially," Judge Easterbrook provided the following example, "[O]ne would suppose that a highway 'extending' from Chicago to Milwaukee goes all the way; just so a relative concentration 'extending' from intake through outlet." *Id*. However, Judge Easterbrook noted in the opinion, "Because Mahurkar and Quinton would not be entitled to any relief under Claims 12 and 25 that they do not obtain under claims 1 and 19, it is unnecessary for me to decide who is right." In re Mahurkar, 831 F.Supp. at 1382. Thus, although Judge Easterbrook did not make a ruling, this Court finds his reasoning to be correct and adopts it.

3. Language in Dispute: "conical tapered tip" and "a truncated cone" FN5

FN5. The parties have agreed that the ruling on claim 12 will be the same as the ruling on claim 19's construction. Thus, the word "cone" is equivalent to the word "conical" for purposes of this Markman decision. The language in dispute in claim 19 is: "...the distal end portion of said tube defining a truncated cone..."

[28] **Does "smooth conical tapered tip" mean (1) a shape with a circular base tapering to a point as in either a centered (right circular) cone or an off-center (oblique circular) cone or (2) a shape tapering evenly on all sides as in a right circular cone?**

Does "cone" mean (1) a shape with a circular base tapering to a point as in either a centered (right circular) cone or an off-center (oblique circular) cone or (2) a shape tapering evenly on all sides as in a right circular cone?

Answer: Both "smooth conical tapered tip" and "cone" mean a shape with a circular base tapering to a point as in either a centered (right circular) cone or an off-center (oblique circular) cone.

a). Claim Language

The parties do not dispute that the limitation in this claim covers an ordinary centered (right circular) cone. Where they do not agree is whether the claim limitations also cover an off-center (oblique circular) cone. A right circular cone, or a centered cone, is a cone in which the apex is aligned with the center of the circle (i.e., an ice cream cone shape). In an oblique circular cone, or an off-center cone, the apex is above the circle, but not directly above the center of the circle. The Court holds the term "cone" includes both a right circular cone and an oblique circular cone. The claim language is helpful because in claim 12, it refers only to a "smooth conical tapered tip," whereas in claim 13, it specifies a type of cone when it states "said conical tip is substantially aligned with the axis of said cylindrical tube." Under the doctrine of claim differentiation, these two claims must mean different things. Thus, under claim 12, the cone may be either a right circular cone or an oblique circular cone and claim 13 is limited to only a right circular cone.

b). Written Description

The specification also supports construction of this claim as not limited to right circular cones. The specification states that in accordance with the invention:

the distal end portion of the tube 11 has a conical tip generally designated 20 which smoothly merges with the cylindrical body of the tube11. *Preferably* the apex of the conical tip 20 is centered on the axis of the cylindrical body of the tube 11 thus serving as a guidance point to uniformly distribute the frictional resistance encountered by the conical tip when the tube is inserted into the body cavity...Since the frictional resistance is uniformly distributed and the conical tip smoothly merges with the body of the tube 11, insertion trauma and kinking are minimized. ('968 patent, col. 3, lines 47-54; 62-64). (Emphasis added).

In order for the frictional resistance to be uniformly distributed, the conical tip must be a right circular cone and not an oblique circular cone. The use of the term "preferably" indicates that the centered cone is Dr. Mahurkar's preferred configuration, but that he also contemplates other types of cones. Because claim 12 does not explicitly recite that the apex of the conical tip is centered on the axis of the cylindrical tube, claim 12 is not limited to this preferred approach. Had Dr. Mahurkar intended to limit claim 12 to right circular cones, he would simply have included the "centered apex" language of claim 13 within claim 12. *See* Rodime PLC v. Seagate Technology, Inc., 174 F.3d 1294, 1305 (Fed.Cir.1999)("Had [the patentee] intended or desired to claim thermal compensation as a function of the positioning means in the asserted claims, it could have done it explicitly as in claim 11").

[29] It is agreed that all of the figures in the '968 patent depict right circular cones, not oblique circular cones. Arrow claims that "conical" must be limited to the described preferred embodiment because "no other embodiment of a tip shape is shown or described in the '968 patent." (Def. Br., at p. 22). Arrow is wrong about the law. A claim term can be limited to the described preferred embodiment only when the specification clearly and unambiguously so limits that term. *See e.g.,* Johnson Worldwide Associates, 175 F.3d at 991. And, "just as the preferred embodiment itself does not limit claim terms....., mere inferences drawn from the description of an embodiment of the invention cannot serve to limit claim terms." Id. at 992. FN6

FN6. Arrow also suggests that the word "cone" is limited to the right circular cone shown in the figures because the '968 patent claims priority from a design application. This argument is contrary to well established law. In Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1565 (Fed.Cir.1991), the Federal Circuit held that Dr. Mahurkar's claims in a utility patent may claim priority from a design application (which shows only figures) so long as the figures in the design application satisfy the written description and enablement requirements of 35 U.S.C. s. 112, para. 1. It is black letter law that a specification (or drawing) need not describe every possible embodiment covered by the claim to satisfy the written description requirement. *See, e.g.,* Johnson Worldwide Assoc., 175 F.3d at 993. *See also* Lampi Corp. v. Am. Power Prods., Inc., 228 F.3d 1365, 1378 (Fed.Cir.2000). Thus, whether the drawings in the design application showed off-center cones in addition to right circular cones is immaterial.

c). Prosecution History

Arrow also seeks to support its narrow construction with passages from the prosecution history contending that Dr. Mahurkar was forced to distinguish a prior art oblique circular cone by limiting his claims to a right circular cone. During prosecution of the '968 patent, Dr. Mahurkar distinguished the Edelman structure. Arrow incorrectly characterizes Edelman's tip as an oblique circular cone. It is not. First, the Edelman tip has a rounded blunt end, not an apex. Second, one entire side of the Edelman tip is flat, and the base, therefore, is not a circle. The Edelman tip structure is perhaps best described as a "beak" or a "nose," not as

a circular cone. The prosecution history statements cited by Arrow, therefore, do not support Arrow's argument.

Perhaps more importantly, the actual grounds upon which Dr. Mahurkar distinguished Edelman was that Edelman lacked the claimed *smooth conical tip,* not just that it lacked a conical tip. Regarding Edelman, Dr. Mahurkar described why his invention differed from Edelman's structure:

The Edelman et al. patent 4,403,983 shows a septum-type dual-lumen catheter in which the septum is inserted as a separate piece; the outer wall of one of the two lumens formed by the insertion of the septum is tapered toward the septum, and the other is cut off "normal to both the septum and the tube axis" (column 2, lines 59-60), thereby forming a sharply stepped tip which would also seem to produce high insertion trauma....None of these septum-type catheters has applicant's smooth conical tapered tip which smoothly merges with the surface of the cylindrical tube ....

(Def. Ex. 2 at NSHN 128765-66.) This passage clearly shows that Dr. Mahurkar's primary concern with the Edelman structure was the sharp step between the tube and the tip. Dr. Mahurkar's claims distinguished this structure by reciting a smooth conical tapered tip that smoothly merges with the tube.

Dr. Mahurkar's statements during the prosecution history, therefore, never limited the word "cone" to right circular cones, and do not constitute a clear and deliberate surrender of claim scope. *See* Northern Telecom Ltd. v. Samsung Electronics Co., Ltd., 215 F.3d 1281, 1294-95 (Fed.Cir.2000)("We cannot conclude that [the defendant] has demonstrated that the patentees-with reasonable clarity and deliberation [citation omitted]-defined 'plasma etching' as excluding ion bombardment.").

d). Dictionary Definition

Medical dictionaries also support Plaintiffs' contention that "conical" is not limited to a centered (right circular) cone. Cone is defined as "a solid figure or body with a circular base tapering to a point." (Dorland's Illustrated Medical Dictionary, Twenty-Sixth Edition). Cone is defined as "a solid figure or body having a circular base and tapering to a point, ..." (Miller-Keane Encyclopedia & Dictionary of Medicine, Nursing & Allied Health (5th Ed.1992)). Cone is defined as "a figure or anatomic structure tapering to a point from a circular base." (Melloni's Illustrated Medical Dictionary (2nd Ed.1985)).

4. Language in Dispute: "Same Side" and "Opposite Side."

[30] **Does "same side of said cylindrical tube" refer to (1) the position on the cylindrical tube relative to the axial divider (i.e., the holes are on the portions of the tube on the same side of the axial divider) or (2) to the position on the cylindrical tube relative to the circumference of the cylindrical tube (i.e., the holes are aligned on the portions of the tube along the length of the tube)?**

Answer: "Same side of said cylindrical tube" refers to the position on the cylindrical tube relative to the axial divider.

Does "opposite side of said cylindrical tube" refer to (1) the position on the cylindrical tube relative to the axial divider (i.e., the holes are on the portions of the tube on different sides of the axial divider) or (2) the position on the cylindrical tube relative to the circumference of the cylindrical tube (i.e., the holes are aligned on the portions of the tube along the length of the tube)?

Answer: "Opposite side of said cylindrical tube" refers to the position on the cylindrical tube relative to the axial divider.

a). Claim Language

These claim limitations concern additional side holes exposing the two lumens of the catheter to the blood stream. The dispute involves the meaning of the phrases "opposite side" and "same side." The Court holds "opposite side" to mean on the other side of the axial divider of the cylindrical tube without reference to any particular point and "same side" to mean on the same side of the axial divider of the tube without reference to any particular point.

The Court's construction is based largely upon the common usage and meaning of the terms "opposite" and "same" as they relate to the term "side." For example, during a tennis match, one player is on one side of the court and his opponent is on the opposite side of the net which divides the court in half. The opponent need not be directly opposite the player to be on the opposite side, he must just be on the other side of the net. Similarly, in a doubles tennis match teammates are considered to play on the same side when they are on the same side of the court as divided by the net. They need not be in the same service box, but just on the same side of the court.

b). Written Description

The illustrations in figs. 1 and 2 of the '968 patent illustrate one embodiment of the claimed side holes. Opening 19, the primary inlet opening for the second lumen, is "said second opening." Multiple holes 21 constitute "at least one side hole circumferentially disposed on the opposite side" of the tube as opening 19, and multiple holes 22 make up "at least one side hole circumferentially disposed on the same side" of the tube as opening 19.

The specification supports Dr. Mahurkar's construction of this claim:

The return holes 21 and the inlet holes 22 are further disposed circumferentially on opposite sides of the divider 12. Thus, there is axial as well as circumferential separation of the inlets and outlets for fluid circulation. ('968 patent, col. 4, lines 10-14).

Holes 21 and 22 are not lined up 180 degrees from each other. In fact holes 22 are much further away from the tip than holes 21. Thus they are on opposite sides of the divider, but not directly across from one another. In this specification there is not a requirement for the outlet hole to be 180 degrees (halfway) from the second opening to be "opposite." There must be holes on the opposite sides of the divider and also some on the same side.

c). Dictionary Definition

The construction of the words "opposite side" and "same side" is simple. The ordinary and accustomed meaning of the words provide their construction. The parties agree the cylindrical tube is divided in half by the axial divider. Therefore, the "opposite side" is simply the opposite side of the divider, and "same side" means the same side of the divider. This does not mean the holes must be exactly 180 degrees apart to be on "opposite sides" nor does it mean the holes must be axially aligned to be on the "same side." Webster's Dictionary defines "side" as "a place, space, or direction with respect to a center or to a line of division (as of an aisle, river, or street)." (Webster's Collegiate Dictionary 1089 (10th ed.1996)).

Common usage of the words here, leads the Court to construct "opposite side" as on the opposite side of the tube as determined by a center line, which in this case is the axial divider. Similarly, "same side" is on the same side of the tube as determined again by the axial divider.

B. CLAIM 13

Claim 13 reads as follows, with language to be construed in bold:

The double lumen catheter as claimed in claim 12, wherein the **apex of said conical tip is substantially aligned with the axis of said cylindrical tube.**

1. Language in Dispute: "the apex of said conical tip is substantially aligned with the axis of said cylindrical tube."

Does Claim 13 mean that (1) the apex is substantially centered on the cylindrical tube, and therefore, the "conical tip" is a centered (right circular) cone or (2) the apex is substantially centered on the cylindrical tube, and therefore, the "conical tip" is centered on the cylindrical tube?

Answer: Claim 13 means that the apex is substantially centered on the cylindrical tube, and therefore, the "conical tip" is a centered (right circular) cone.

Claim 13 is a dependent claim. The basis for the Court's holding is found in the Court's discussion of claim 12 at III. A. 3 *supra*.

C. CLAIM 19

Claim 19 reads as follows, with language to be construed in bold:

A double lumen catheter comprising an elongated **unitary tube** including an **integral septum** extending axially along the entire length of the tube and dividing the interior of said tube into a first and a second lumen, the outer circumference of said tube converging smoothly at the distal end portion of said tube defining a truncated cone, the first lumen opening at the truncated apex of said cone, and the second lumen being shorter in axial length than the first lumen and opening upon the outer circumference of said tube, said tube having a uniform diameter from its distal end portion to proximally beyond the opening of the second lumen upon the outer circumference.

1. Language in Dispute: "A double lumen catheter **comprising an elongated unitary tube including an integral septum..."**

[31] **Does "unitary tube" mean (1) the tube and tip are a single unit or (2) a tube and tip are of single-piece construction (i.e. integrally formed)?**

Answer: "Unitary tube" means the tube and tip are a single unit.

a). Claim Language

The issue in this claim is whether the term "unitary" requires the tube and tip to be formed from one piece

of material. The Court answers this question no.

The claim language says "elongated unitary tube including integral septum." Integral means one-piece formation, as opposed to bonded, which is a two-piece construction. The patent does not say integral tube including integral septum. If that were the case it would be clear that the claim only covers a tube formed from a single piece and a septum formed from one piece. However, that is not what we have in claim 19.

The words integral and unitary are two different terms which are presumed to have two different meanings. Comark Communications, Inc., 156 F.3d at 1182. The patent, the prosecution history and the common usage of the terms all suggest "integral" means being formed from one piece of material while "unitary" requires the object be a single unit. Therefore, the adjective "unitary" describing the tube, requires that the elongated tube including its tip and integrated septum, be a single unit in the completed catheter product.

b). Written Description

The specification in the patent supports the construction that the elongated tube must be one unit in the completed catheter, but may be manufactured either integrally or by bonding. The specification shows an example of a unitary tube in the figures and states the tube can be made from one piece of material or multiple pieces joined together to form one unit:

It is readily apparent to persons of ordinary skill in the art that the tip 20 as shown in FIG. 7 is easily formed from thermo-plastic material. The tip 20 including the relative concentration of material 23 is easily *molded and bonded or is integrally formed* from the cylindrical tube 11 by the use of internal and external mandrels and the application of heat by any number of conventional means such as RF forming, thermal forming, or infrared forming. ('968 patent, col. 4, lines 29-37). (Emphasis added).

Thus, the written description in the patent corroborates Dr. Mahurkar's construction.

c). Prosecution History

Arrow contends the word "unitary" requires that the entire tube, including the tip, be constructed from a single piece of material. In support of this construction, Arrow cites a passage from the prosecution history which includes a discussion of the "unitary" and "integral septum" limitations:

Claim 21[now claim 19] further recites a double lumen catheter comprising an elongated *unitary* tube including an integral divider. Edelman et al. does not disclose a unitary structure. The unitary structure prevents mis-matching of components, the clotting of blood and tips breaking off into the patient. (Def. Ex. 2 at NSHN 128717).

This passage cites the advantages of the unitary structure, but does not limit the construction of the unitary tube to integral formation from a single material. This passage was presented by Dr. Mahurkar to demonstrate that the Edelman catheter is not unitary and his is. He was not equating the word "unitary" with "integral" but rather was equating "unitary" with a single unit, and explaining that the Edelman catheter has multiple pieces (the septum and the cylinder) that are not sealed. (See Edelman et al. Patent No. 4,403,983, col. 2 lines 29-32 and 46-49).

In another section from the prosecution history it is equally apparent that the word "unitary" means a single unit. In this portion of the patent prosecution Dr. Mahurkar described the tube and tip as "unitary"and then

stated that the septum is "of one-piece construction with said tube." (Def. Ex. 2 at NSHN 128764). If as Arrow contends, the words "unitary" and "integral" are synonymous, Dr. Mahurkar would not have found it necessary to describe the tube and septum separately with different adjectives. The prosecution history reinforces that the ordinary meaning of "unitary" is a single unit.

d). Dictionary Definition

The word "unitary" is best construed by its ordinary usage and accustomed meaning. Webster's defines "unitary" as "having the character of a unit: whole." (Webster's II New Riverside University Dictionary 1262 (1994)). Therefore, the word "unitary" an adjective describing the elongated tube, provides that the tube, including the septum, be a single unit in the catheter.

e). Prior Litigation

As discussed *supra,* the '968 patent was also the subject of previous litigation. Judge Easterbrook analyzed claim 19 in terms of its best mode, but did not decide the issue before this Court. In re Mahurkar, 831 F.Supp. at 1378.

2. Language in Dispute: "An integral septum."

[32] **Does "septum" mean (1) a dividing wall or (2) a flat divider?**

Answer: "Septum" means a dividing wall.

a). Claim Language

The issue is whether the septum is limited to being flat. The Court holds the septum extending along the tube and dividing the tube into first and second lumens is not limited to a flat divider. The claim language provides that there must be a septum which is integral with the tube which divides the interior of the tube into the "first lumen" and the "second lumen." The claim language does not specify the type of septum, only that it must be integral. Therefore, the Court will not read another adjective into the claim language but will instead construe "septum" in accordance with its ordinary usage and accustomed meaning. The ordinary meaning of "septum" is divider.

b). Written Description

The specification supports the construction that a "septum" is a divider:

The tube 11 is circular in cross section... And has an internal divider 12 defining a return lumen 13 and an inlet lumen 14 within the interior of the hollow tube. ('968 patent col. 3, lines 17-20).

This language does not specify what type of divider must divide the tube into two lumens. Furthermore, the specification does not limit the "septum" of claim 19 to a planar septum, it merely discloses one preferred embodiment.

That Dr. Mahurkar intended for claim 19 to cover cathaters with a non-planar septum is made particularly clear by comparing claim 19 to the other independent claims of the '968 patent: claims 1, 12, and 25. Claims 1 and 25, unlike claim 19, both explicitly recite a "planar septum," and claim 12 recites a "planar axial

divider." The patentee's use of the limiting adjective "planar" in some claims, but not others, must be given meaning. *See* Karlin, 177 F.3d at 972 ("different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope").

c). Dictionary Definition

The dictionary defines "septum" as "a dividing wall or membrane." (Webster's Collegiate Dictionary 1068 (10th ed.1996)). The dictionary definition supports Dr. Mahurkar's construction of "septum" as a dividerthat separates the interior of the tube into two lumens. Additionally, a medical dictionary definition of "septum" also supports the Plaintiffs' proposed construction. In Stedman's Medical Dictionary, "septum" is defined as "A thin wall dividing two cavities or masses of softer tissue." (Stedman's Medical Dictionary 1599 (26th ed.1995)). For example, the septum of the nasal passage divides the nose into two cavities. (Id).

d). Prior Litigation

Arrow contends Judge Easterbrook's decision in *In re Mahurkar* judicially estops Plaintiffs from asserting claim 19 is not limited to a planar septum. This Court disagrees. In *In re Mahurkar,* Judge Easterbrook wrote, " the essential question concerning infringement came down to a disagreement about the meaning of language in the '968 patent concerning the septum." In re Mahurkar, 831 F.Supp. at 1358. However, Judge Easterbrook was never required to construe the meaning of septum in claim 19 because he found IMPRA infringed without having to do so. IMPRA argued its catheter did not infringe claims 1 and 19 because the septum in its device was not continuous through the tip. Id. at 1358. Judge Easterbrook noted that, " [a] 'septum' is something dividing two lumens; because at the tip IMPRA's device has only one lumen, it has no septum there." *Id*. However, Judge Easterbrook determined that Dr. Mahurkar's invention also had its septum "moved out of the way at the tip." *Id*. Thus, "the invention claimed and described in the patent has exactly the deflection that IMPRA's device does...IMPRA's device literally infringes." *Id*. Therefore, this Court's holding that the septum in claim 19 should be construed as a divider which is not limited to being flat is not inconsistent with Judge Easterbrook's decision in *In re Mahurkar,* because Judge Easterbrook never decided this issue.

Arrow argues Dr. Mahurkar limited all his claims to a flat septum in *In re Mahurkar,* in order to claim priority from a design application. This is simply not what happened. The priority issue turned on whether the claims of the '968 patent, including those requiring a planar septum, were supported by the drawings presented in the design application. Judge Easterbrook's decision was based on his finding that the drawings in the design application satisfied the written description requirement of s. 112. *Id*. at 1362. Judge Easterbrook found the claims of the '968 patent were supported by the drawings in the design application. Id. He did not limit the patent to only that which was shown in the drawings.

Similarly, Arrow quotes a portion of the *In re Mahurkar* opinion relating to an inequitable conduct defense:

But only a dunderhead looking at figures 6 and 7 of the original design application would have supposed that the septum is discontinuous, or curved in places not depicted...The design drawings alone therefore imply a unitary, planar, full-length septum. In re Mahurkar, 831 F.Supp. at 1381-82. (Emphasis in original).

When Judge Easterbrook rejected the inequitable conduct defense, he was not limiting claim 19 to a flat septum as shown in the drawings. This passage does not discuss whether all the claims of the patent, including claim 19 are limited to a flat septum, only that the drawings in the embodiment illustrate a flat septum. Claim 19 is certainly not limited to the drawings in the specification. *See* Karlin Technology Inc.,

177 F.3d at 972.

Arrow also cites passages from Judge Easterbrook's opinion and a Federal Circuit opinion that describe Dr. Mahurkar's commercial embodiment and his preferred design. These passages were introductory to describe Dr. Mahurkar's advance over other catheters, and do not concern the specific claim presented in claim 19.

Finally, Arrow argues that a planar septum was crucial to the court's finding that the '968 patent was valid over the prior art regarding the Blake balloon catheter. Judge Easterbrook did hold that the '968 patent was valid over Blake's prior art, but not because of a planar septum. The reason Judge Easterbrook held the '968 patent was valid over the prior art was because he found Blake's catheter to be an "utterly different beast" from Dr. Mahurkar's. Id. at 1376. He also stated that in Blake, the " lumens are not of equal size, are not D-shaped, there is no axial separation to improve flow (Blake was uninterested in flow), no details to prevent clotting." Id. However, this passage was not a holding that claim 19 is limited to the double D configuration or a planar septum.

IV. CLAIM INTERPRETATION-THE '561 PATENT

The elements of the '561 patent requiring construction by the Court are all found in Claims 1, 10, 21, 34, and 42.FN7

FN7. Some of the terms in the '561 patent requiring construction appear in multiple claims. Identical claim terms appearing in multiple claims of a patent, however, "must be construed consistently." Southwall Technologies, 54 F.3d at 1574. Therefore, the Court, as it did with the '968 patent, will only address each disputed term the first time it appears in the patent and the construction of the term will apply for each claim where the term is found.

A. CLAIM 1

Claim 1 states as follows, with language to be construed in bold:

A dual-lumen catheter assembly comprising:

a dual-lumen **catheter** having a distal end and a proximal end, **flow diversion means** having one end fastened to the proximal end of said catheter, and a flexible extension of tubes each having one end fastened to the opposite end of said flow diversion means from said catheter, each of said extension tubes being **bent back toward the distal end of said catheter** to form a bend having a predetermined shape, each bend being adapted to flex and deform from said predetermined shape in response to removal of said external force.

1. Language in Dispute: "catheter"

[33] **Does "catheter" mean (1) the portion of the assembly inserted into the patient or (2) the structure distal to the flow diversion means or connecting means?**

Answer: "Catheter" means the portion of the assembly intended to be inserted into the patient.

a). Claim Language

The Court must determine the meaning of "catheter." Claim 1 begins with the components of a dual-lumen catheter assembly: a catheter, flow diversion means, and a pair of flexible extension tubes. The claim language supports the construction proposed by the Plaintiffs because it says that a catheter assembly requires a catheter and other items. Therefore the term catheter must mean only that portion of the catheter assembly intended to be placed into the body and not the entire apparatus which contains other parts as described by the claim.

A syringe contains a needle and a dispensing tube. We commonly describe the "needle" as the portion of the syringe from the tip up to the dispensing tube. Although on each person the portion of the needle that goes into the flesh may vary, the needle is still considered to be the part of the syringe that could possibly enter the skin. Similarly, the term "catheter" is that portion of the catheter assembly which is intended to be inserted into the patient.

b). Written Description

The specification is consistent with defining "catheter" as that portion of the catheter assembly which is intended to be inserted into the body. The background of the invention section supports construing the word "catheter" as the tube intended to be inserted into the patient. In this section it describes that "catheters" are "routinely allowed to remain in patients" for weeks or months. ('561 patent, col. 1, lines 32-34). Additionally, the background section explains the potential problems with catheters including the potential for them to become dislodged or cause pain or discomfort in patients because of continual movement within the vein. ('561 patent, col. 2, lines 1-5).

The summary of the invention also supports construing the word "catheter" as the tube intended to be placed into the patient's body. The summary provides that the primary object of the invention is " to provide an improved dual-lumen catheter-connecting system which permits the catheter to remain relatively stable during the entire time the *catheter remains inserted in the patient*." ('561 patent, col. 2, lines 34-38). (Emphasis added). Furthermore, throughout the summary of the invention, reference is made to a catheter which is inserted into the patient's vein. For example: "... improves the comfort level of the patient in whom the catheter is inserted" ('561 patent, col. 2, lines 42-43); " regardless of the particular vein into which the catheter is inserted" ('561 patent, col. 2, lines 54-55); and "the catheter is inserted in a jugular vein" ('561 patent, col. 3, lines 3-5).

c). Dictionary Definition

The dictionary definition of "catheter" lends even more support to constructing "catheter" to mean the portion of the assembly intended to be inserted into the patient. Webster's II New Riverside University Dictionary defines "catheter" as " a slender, flexible tube inserted into a bodily channel, as a vein..." (Webster's II New Riverside University Dictionary 238 (1994)).

In addition, a medical dictionary definition is also consistent with this construction. Stedman's Medical Dictionary defines "catheter" as " a tubular instrument to allow passage of fluid from or into a body cavity." (Stedman's Medical Dictionary 292 (26th ed.1995)). The "catheter" is the tube inserted into the patient which makes it possible to extract fluid from or pass fluid into body cavities.

2. Language in Dispute: "flow diversion means"

[34] **Does the "flow diversion means" function to (1) divert fluid flow from the "dual-lumen catheter" into the "pair of flexible extension tubes" or to (2) divert fluid flow from the "dual lumen catheter" so that the flow paths diverge?**

Answer: The "flow diversion means" function to divert fluid flow from the "dual-lumen catheter" into the "pair of flexible extension tubes."

a). Claim Language

The claim language lists "flow diversion means" as one of the components of the catheter assembly. The claim says the catheter assembly includes "flow diversion means having one end fastened to the proximal end of said catheter." Claim 1 is written in means-plus-function format. In order to construe the function portion of the element, the Court applies the normal claim construction rules. Chiuminatta Concrete, 145 F.3d at 1308. The function portion of the element is "flow diversion." The parties agree that the corresponding structure for "flow diversion means" is Y-shaped connectors and equivalents thereof. The parties disagree, however, about the construction of the function portion of the means-plus-function clause: "flow diversion."

The common and ordinary usage of the phrase "flow diversion" is, directing a stream or other moving liquid. In this case the diversion or directing of the flow is between the catheter and the two extension tubes. The plain meaning of the claim is clear; the flow diversion means (the Y-connector) diverts fluid flow from the two lumens in the "dual-lumen catheter" into the "pair of flexible extension tubes."

3. Language in Dispute: "being bent back toward the distal end of said catheter"

[35] **Do the tubes being "bent back toward the distal end of said catheter" mean that (1) the tubes must be bent toward (i.e., in the direction of) the distal end of the catheter or (2) the tubes be bent so that the proximal ends of the extension tubes are facing the distal end of the catheter?**

Answer: The tubes being "bent back toward the distal end of said catheter" means that the tubes must be bent toward (i.e., in the direction of) the distal end of the catheter.

a). Claim Language

Claim 1 lists what components are necessary for a catheter assembly. Among those mentioned are a "pair of flexible extension tubes." The claim language says each of these tubes have three characteristics: (1) they are "bent back toward the distal end"; (2) they "form a bend having a predetermined shape"; and (3) each bend is "adapted to flex and deform from said predetermined shape in response to an external force and...to return to [the] predetermined shape in response to removal of said external force."

Both parties agree that the extension tubes should have a memorized bend and that the tubes are resilient so that their shape can be changed by force, but that once the force is removed, the tubes will return to the original shape. Thus, the only issue for the Court to decide is whether these flexible tubes must have a memorized bend of at least 180 degrees. The Court answers this question no.

The ordinary meaning of "bend" is to form a curve. For example, a wire can be bent from a straight line into a curve, or a gymnast can arch her back and place her hands on a mat to perform a "back bend" or a "back handspring." The word "bend" in claim 1 is followed by a directional modifier describing the manner

in which the flexible tubes should be bent. The claim language says they should "bend back toward the distal end." The term "back" ordinarily means the rear or from where something just came and "toward" means in a specific direction (i.e., together the words "back toward" mean in the direction of the rear). Therefore, in this claim, the common meaning of the words is that the flexible tubes should curve in the direction of the rear, or the distal end. This does not mean they must curve to at least 180 degrees. Again consider a gymnast's body, this time as a flexible tube. When a gymnast performs a "back bend" reaching her arms back (toward the rear) over her head and toward the ground, her body becomes a curve, she may place her hands in a position such that her body is curved 180 degrees, or so that her body is curved 150 degrees. No matter what the exact placement of her hands she still has bent back toward the rear and caused her body to become curved. That is exactly what we have in this claim. So long as the flexible tubes are bent back toward the distal end, toward the catheter, they are not required to be at least 180 degrees, or facing the distal end of the catheter.

Furthermore, the doctrine of claim differentiation requires Claim 1 to be read without a limitation of the bend being at least 180 degrees. The claim language in Claim 8 reads, " The catheter assembly of claim 1 wherein said extension tubes are generally U-shaped." If claim 1 were meant to require a bend of at least 180 degrees, then claim 8 would conflict with claim 1 and violate the doctrine of claim differentiation. This is because claim 8 limits the bend to a shape which is generally 180 degrees, therefore it contemplates claim 1 can have a bend of potentially less than 180 degrees. Thus, in order not to have claim 8 conflict with claim 1, the tubes in claim 1 cannot be limited to a bend of at least 180 degrees.

b). Written Description

It is clear in the specification that the extension tubes must bend back toward the catheter tip in order to accomplish their purpose of making the catheter assembly more comfortable for the patient. The extension tubes are bent back toward the distal end of the catheter so that the catheter "can be accommodated in a small area around the access site on the patient's body." ('561 patent, col. 5, lines 60-61). Furthermore, the bend in the tubes also enables patients to change clothing and move about without projections interfering. ('561 patent, col. 5, lines 65-68 and col. 6, lines 1-3). Each of these goals can be achieved without limiting the bend of the tubes to at least 180 degrees. A bend short of 180 degrees would still provide for a patient to be able to change clothing and allow the catheter to be contained to a small area.

B. CLAIM 21

Claim 21 reads as follows, with language to be construed in bold:

A method of preparing a patient for extracorporaeal blood treatment comprising the steps of inserting into a vein selected from the group consisting of the jugular, subclavian and femoral veins of the patient, the distal end portion of a dual-lumen catheter assembly having flow diversion means having one end fastened to the proximal end of said catheter, a pair of flexible extension tubes each having one end fastened to the opposite end of said flow diversion means from said catheter, each of said extension tubes being bent back toward the distal end of said catheter and **extending alongside said flow diversion means** to form a bend having a predetermined shape, each bend being adapted to flex and deform from said predetermined shape in response to an external force and being adapted to return to said predetermined shape in response to removal of said external force, flow control means for controlling by the flow of blood between said dual-lumen catheter and an extracorporeal blood treatment unit, and coupling means for coupling said extension tubes to said blood treatment unit, and taping said flow diversion means and extension tubes to the skin of the patient.

1. Language in Dispute: "extending alongside said flow diversion means"

[36] **Does extending "alongside" said flow diversion means mean (1) that the extension tubes can extend on either opposite sides or the same side of the Y-connector or (2) that each extension tube extends on the opposite side of the Y-connector?**

Answer: Extending "alongside said flow diversion means" means that the extension tubes can extend on either opposite sides or the same side of the Y-connector.

a). Claim Language

The claim language calls for the flexible extension tubes to extend "alongside" the "flow diversion means," the Y-connector, to form a bend. The Court having already determined the meaning of "flow diversion means," must now construe the word "alongside." The common and ordinary meaning of "alongside" is, next to a side or being positioned on a side. In other words, the claim language in claim 21 means the bent extension tubes must extend next to a side of the catheter, or be positioned on a side of the catheter. The word "alongside" does not specify which side; it can be the same side or the opposite side. Thus, the extension tubes can extend along opposite sides or on the same side and still fall within the ordinary and accustomed meaning of the term "alongside."

For example when sportscasters are announcing a horse race and they say "Point Given" and "AP Valentine" are coming around the turn right "alongside" "Congaree", it is possible that the two horses are both on the left side of "Congaree," that they are both on the right side of "Congaree," or that "AP Valentine" is on the left of "Congaree" and "Point Given" on the right and vice versa. Thus, the two horses may be alongside the predicted winner if they are on the same side or on opposite sides of "Congaree."

b). Written Description

The specification of the '561 patent supports construing the phrase " alongside said flow diversion means" as the extension tube can extend on either opposite sides or the same side of the Y-connector. The specification reads, " the extension tubes are bent back toward the distal end of the catheter, *preferably extending along the sides of the catheter* ..." ('561 patent, col. 5, lines 56-57). (Emphasis added). The term "preferably" conveys the message that a particular method is desirable or a first choice; it does not convey the idea that something is mandatory. Thus, Dr. Mahurkar prefers the tubes extend along the opposite sides of the catheter, but has contemplated embodiments where the two extension tubes can extend along the same side of the Y-connector.

c). Dictionary Definition

The dictionary definition also supports construing the claim language extension tubes "extending alongside said flow diversion means" as the extension tubes can extend on either opposite sides or the same side of the Y-connector. The dictionary definition of "alongside" is "along, near, at or to the side." (Webster's II New Riverside University Dictionary 95 (1994)). Again, there is no specification as to whether something must be on the same side or the opposite side. Thus, the extension tubes may extend along the same side or opposite sides of the said "flow diversion means."

C. CLAIM 34

Claim 34 reads as follows, with language to be construed in bold:

A dual-lumen catheter assembly comprising a dual-lumen catheter, and **connecting means** attached to the proximal end of said catheter and forming a pair of internal passageways which communicate at one end thereof with the dual lumens in said catheter, said passageways curving back toward the distal end of said catheter so that forces exerted on said connecting means at the other ends of said passageways will tend to move said catheter in a direction opposite that of said exerted forces.

1. Language in Dispute: " connecting means"

[37] **Do the disclosed structures corresponding to the "connecting means" include (1) a Y-connector fastened to bent extension tubes and a unitary connecting member or (2) a unitary connecting member only, or, if the Court finds sufficiently disclosed additional corresponding structure, also a Y-connector fastened to extension tubes that do not straighten out in response to forces?**

Answer: The disclosed structures corresponding to the "connecting means" include a Y-connector fastened to bent extension tubes and a unitary connecting member.

a). Claim Language

"Connecting means" is a means-plus-function clause. The function is connecting to the proximal end of that portion of the assembly that is inserted into the patient's body and forming a pair of internal passageways which communicate at one end thereof with the dual lumens in the catheter.

b). Written Description

The specification discloses two different corresponding structures which are linked to the function. First, the specification discloses a Y-shaped connector or hub (element 30) connected to two extension tubes (elements 40 and 41) that curve back toward the distal end of the catheter. Second, the specification discloses using a " a unitary connecting member" instead of the hub and two extension tubes:

...the curved passageways provided by [the] extension tubes may instead be formed by a unitary connecting member fastened to the proximal end of the dual-lumen catheter. More specifically, the unitary connecting member may form two internal U-shaped passageways, each of which is in communication with one of the lumens of the catheter. ('561 patent, col. 8, lines 14-22).

Thus, the "connecting means" may be: (1) a Y-shaped connector connected to extension tubes that curve back toward the distal end of the catheter, and equivalents thereof; and (2) a unitary connecting member forming two internal U-shaped passageways, each of which is in communication with one of the lumens of the catheter, and equivalents thereof. Other details of the specific structures mentioned in the specification such as the size of the hub and the materials used to make the extension tubes, are details "unrelated to the recited function" and therefore do not limit the claim. Chiuminatta Concrete, 145 F.3d at 1308.

V. CONCLUSION

The Markman hearing has been concluded, the claims have been construed and the saga continues in conformity with this opinion.

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United States Patent [19]

Mahurkar

[11] Patent Number: 4,583,968

[45] Date of Patent: Apr. 22, 1986

[54] SMOOTH BORE DOUBLE LUMEN CATHETER

[76] Inventor: Sakharam D. Mahurkar, 6171 N. Sheridan, Suite 1112, Chicago, Ill. 60660

[21] Appl. No.: 641,187

[22] Filed: Aug. 15, 1984

Related U.S. Application Data

[63] Continuation of Ser. No. 538,675, Oct. 3, 1983.

[51] Int. Cl.[4] A61M 5/00

[52] U.S. Cl. 604/43; 604/280

[58] Field of Search 604/43-45, 604/280

[56] References Cited

U.S. PATENT DOCUMENTS

D. 250,349	11/1978	McFarlane	D24/54
D. 256,817	9/1980	Clinton	D24/54
D. 272,201	6/1984	Mahurkar	
998,139	7/1911	Hollins	24/24 A
1,280,647	10/1918	Nyvall	128/214 R X
2,175,726	10/1939	Gebauer	128/249 B
2,474,665	6/1949	Gustine	128/DIG. 3
2,564,977	8/1951	Hai Hu	128/221 X
2,590,895	4/1952	Scarpelmo	128/221
2,625,932	1/1953	Salisbury	128/214.2
3,324,855	6/1967	Czorny et al.	128/214.4
3,488,152	8/1969	Sorenson	128/214.4
3,598,591	12/1970	MacGregor	128/214.4
3,804,097	4/1974	Rudie	128/350 R
4,017,666	6/1977	Dunn	128/214 R
4,056,860	6/1978	Nell Anghlia	128/214.4
4,098,275	7/1978	Consalvo	128/221 X
4,099,528	7/1978	Sorenson et al.	128/214.4
4,134,402	1/1979	Mahurkar	128/221 X
4,146,024	3/1979	Terstegen et al.	128/214.4
4,181,069	12/1979	Jacobsen et al.	128/214 R
4,202,332	5/1980	Terstegen et al.	128/221 X
4,203,436	5/1980	Grimsrud	128/214 R
4,210,555	7/1981	Bogue et al.	128/214.4
4,356,036	6/1982	Leska et al.	128/214 R X
4,382,631	5/1983	Johnson	604/264
4,401,983	8/1983	Edelman et al.	604/43
4,451,252	5/1984	Martin	604/43
4,492,696	1/1985	Udall	604/43

FOREIGN PATENT DOCUMENTS

834211	2/1976	Belgium	128/221
1092927	1/1981	Canada	604/43
30089	8/1982	Canada .	
36642	9/1981	European Pat. Off.	604/43
2259565	6/1974	Fed. Rep. of Germany	128/221
MR19946	6/1962	Fed. Rep. of Germany .	
992193	6/1951	France	128/214.2
821344	4/1980	France .	
55-81771	7/1980	Japan	128/348
1419702	12/1975	United Kingdom	128/221
1005219	3/1983	United Kingdom .	

OTHER PUBLICATIONS

McIntosh et al., "Double Lumen Catheter," *JAMA*, Feb. 21, 1959, pp. 737/835—118/836.

Dorland's Illustrated Medical Dictionary, 25th Ed., W. B. Saunders Co., Philadelphia, 1974, p. 274.

Brenner & Rector, *The Kidney*, vol. III, W. B. Saunders Co., Philadelphia, 1976, p. 164.

Tuhokai, J., "Single Two-Lumen Cannula Dialysis", Aug., 1974.

ASAIO Abstracts, vol. 5, 22nd Annual Meeting, San Francisco Calif., Apr. 3-3, 1976, p. 52.

Primary Examiner—Dalton L. Truluck

Attorney, Agent, or Firm—Leydig, Voit & Mayer, Ltd.

[57] ABSTRACT

A double-current catheter having an elongated cylindrical tube for injection and removal of fluid is provided with a smooth conical tapered tip that smoothly merges with the cylindrical surface of the tube so that insertion trauma and the possibility of kinking are minimized. To provide improved dilator characteristics, preferably the tip includes a relative concentration of material for rigidity, the conical taper is gradual and the apex of the conical tip is substantially centered on the axis of the cylindrical tube. To promote fluid flow, the cylindrical tube preferably includes an internal planar divider defining two "D" shaped lumens. A first lumen extends from the proximal end of the cylindrical tube to a first opening at the distal end, and the second lumen extends from the proximal end to a side opening in the cylindrical surface of the tube. Preferably additional side holes for the lumens are provided to enhance fluid flow.

25 Claims, 7 Drawing Figures

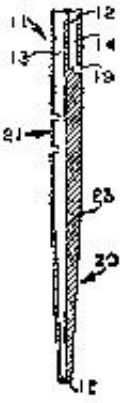

EXHIBIT A

EXHIBIT A

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Fig 1

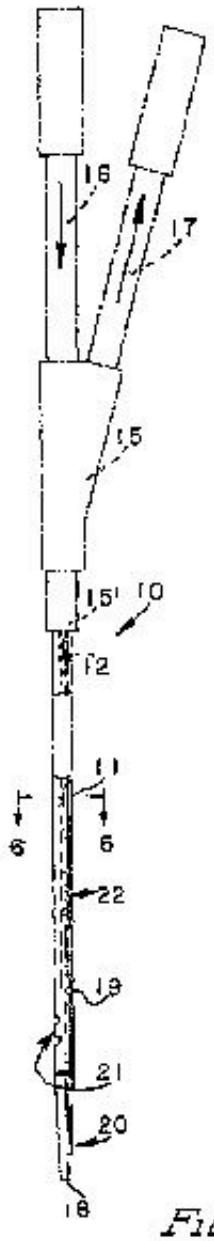

Fig 2

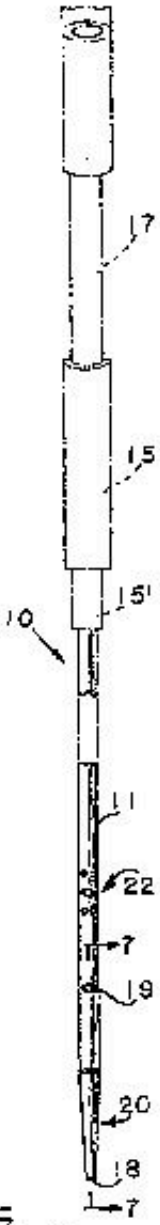

Fig 3

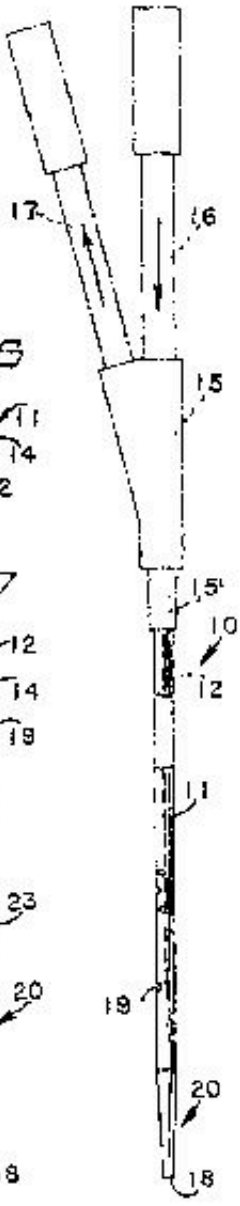

Fig 4

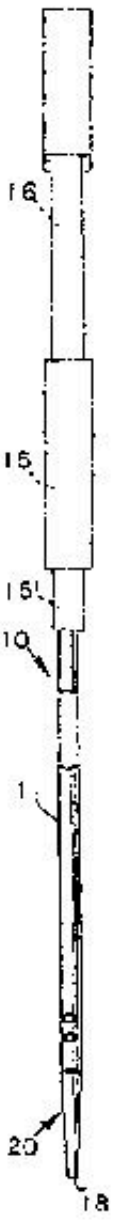

Fig 6

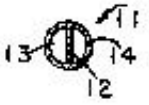

Fig 7

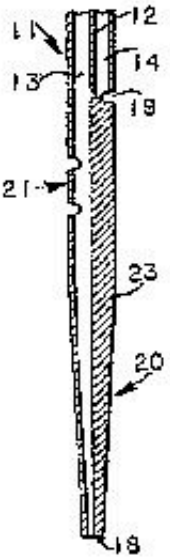

Fig 5

SMOOTH BORE DOUBLE LUMEN CATHETER

RELATED APPLICATIONS

The present application is a continuing application of Ser. No. 438,671 filed Oct. 3, 1983.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to surgical instruments for withdrawing fluids from or introducing fluids into a cavity of the body.

2. Description of the Related Art

As is well known, a catheter is a tubular, flexible, surgical instrument for withdrawing fluids from (or introducing fluids into) a cavity of the body. A double-current catheter is a catheter having two channels, one for injection and one for removal of fluid. *Dorland's Illustrated Medical Dictionary Twenty-Fifth Edition* (W. B. Saunders, Philadelphia 1974), p. 274. As is well known, a double-current catheter is used for removing blood from a fistula or vein for processing in a dialysis machine and returning the processed blood back to the fistula or vein. A double-current catheter suitable for this purpose is disclosed in Mahurkar, U.S. Pat. No. 4,134,402 issued Jan. 16, 1979. Mahurkar U.S. Pat. No. 4,134,402 discloses a double lumen concentric flow hemodialysis needle and cannula having contiguous lumens of different lengths formed by dividing a rotary straight tube, the shorter lumen acting as a blood intake lumen and the longer acting as a blood return lumen. Semi-circular lumens provide a minimal resistance to blood flow resulting in a smaller but highly efficient catheter in comparison to a coaxial double-current catheter. Hemodialysis requires, for example, a blood flow rate of about 200 ml/min or more and flow resistance less than about 100 mm of mercury.

There are numerous other United States Patents disclosing double-current catheters for hemodialysis and evidencing a long-felt need for a small, functionally efficient catheter having a minimum of insertion trauma and potential for clotting. McLaughlin, U.S. Pat. No. 4,056,860 issued June 27, 1978 discloses a coaxial hemodialysis catheter said to allow a step enlargement of the opening of a blood vessel to avoid tearing and rupture of the side walls. A simultaneous flow device incorporates a hub with an extension conduit and a valve therein for receipt of a needle therethrough. The extension conduit is of sufficient size to allow the passage of the needle therethrough adjacent the interior side walls thereof with an attendant extension thereof from its opening. The needle with the extension conduit is adapted for combined insertion within a blood vessel, after which it can be withdrawn while the valve prevents the backflow of blood through the axial passage of the hub. A coaxial flow device can then be inserted within the hub conduit.

Sorenson et al., U.S. Pat. No. 4,099,528 issued July 11, 1978 discloses a coaxial double lumen cannula mounted upon a hub and having a central stylet needle for penetrating a patient's vein and which is retractable after penetration.

Grimsrud, U.S. Pat. No. 4,103,436 issued May 23, 1978 discloses a hollow hypodermic needle with a divider for providing a first channel for removal of blood for treatment from a punctured blood vessel and a second channel for returning the treated blood to the blood vessel.

Utsumun, U.S. Pat. No. 4,385,631 issued May 31, 1983 discloses a hemodialysis catheter for puncturing blood vessels which includes a section insertable through a puncture opening into a blood vessel and a hose line following thereafter.

Jacobsen et al., U.S. Pat. No. 4,180,068 issued Dec. 25, 1979 discloses a double-current hemodialysis catheter comprising a primary tube and an internal divider which also functions as a trocar and valve. The primary tube has a side opening for receiving blood and a central opening at the distal end of the primary tube. The internal divider includes a cutting end which protrudes from the distal opening when the divider is longitudically moved to an insert position. In the insert position, blood flow is blocked.

Mahurkar, U.S. Pat. No. Des. 272,651 issued Feb. 14, 1984 discloses a double lumen catheter having an outlet lumen which has an opening at the tip of the catheter and a shorter inlet lumen which terminates in a bevel substantially displaced from the tip.

SUMMARY OF THE INVENTION

The primary object of the invention is to provide an efficient dual lumen catheter having minimal insertion trauma and a minimal potential for clotting.

Another object of the invention is to provide a dual lumen catheter which is an effective dilator for soft tissue and veins.

In accordance with the invention, a dual lumen catheter has a smooth conical tapered tip that smoothly merges with the catheter body so that insertion of the catheter is facilitated. The tip guidance point is located at the center of the conical tip for uniform distribution of frictional resistance and minimization of insertion trauma and binding. The conical tapered tip comprises a relative concentration of material to impart relative rigidity so that the tip functions as an effective dilator for soft tissue and veins. Semicircular lumens insure non-stable laminar flow and prevent clotting. The smooth bore double lumen catheter is particularly advantageous when a guarding procedure or blind technique must be used, for example, to reach a vein under the collar bone or neck.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages of the invention will become apparent from the following detailed description and the accompanying drawings, in which:

FIG. 1 is a front elevational view of a smooth bore double lumen catheter according to the present invention;

FIG. 2 is a right side elevational view of the smooth bore double lumen catheter illustrated in FIG. 1;

FIG. 3 is a rear elevational view of the smooth bore double lumen catheter illustrated in FIG. 1;

FIG. 4 is a left side elevational view of the smooth bore double lumen catheter illustrated in FIG. 1;

FIG. 5 is a bottom view of the smooth bore double lumen catheter illustrated in FIG. 1;

FIG. 6 is a view in section of the smooth bore double lumen catheter illustrated in FIG. 1 taken along line 6--6 thereof; and

FIG. 7 is a view in section of the smooth bore double lumen catheter illustrated in FIG. 1 taken along line 7--7 shown in FIG. 2.

While the invention will be described in connection with a certain preferred embodiment, it will be understood that it is not intended to limit the invention to that particular embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Turning now to the drawings, FIGS. 1-6 show the various external views of a smooth bore double lumen catheter, generally designated 10, in accordance with the present invention. As is conventional for a double-current catheter, the double lumen catheter 10 has a elongated hollow tube 11 which is inserted into a cavity of the body such as a fistula or vein. The tube 11 is circular in cross section, as specifically shown in FIG. 6, and has an internal divider 12 defining a return lumen 13 and an inlet lumen 14 within the interior of the hollow tube 11. The lumens 13 and 14 are semicircular or "D" shaped which minimizes resistance to fluid flow. As is conventional for this type of dual lumen construction, the divider 12 extends axially along the tube 11 from a branching connector 15. The branching connector 15 connects the distal end portions of the return lumen 13 and the inlet lumen 14 to respective fluid return and inlet lines 16 and 17 which are, for example, respective venous and arterial lines of a dialysis circuit. The preferred direction of fluid circulation is indicated by heavy arrows in FIGS. 1 and 3. The branching connector 15 includes a coaxial sleeve 15' at the junction of the tube 11 and the connector 16. The sleeve 15' acts as a strain relief and also prevents kinking of the tube 11 at the junction.

The hollow tube 11 includes openings or apertures at the distal end portions of the lumens 13, 14 to permit the flow of fluid between a body cavity (not shown) and the lumens. The return lumen 13 extends along the entire length of the tube 11 to an aperture or opening 18 at the distal end or tip of the tube 11 as is more clearly shown in FIG. 7. The inlet lumen 14 is shorter than the return lumen 13 and terminates at its distal end at an aperture or opening 19 that is in the side of the tube 11 and is substantially displaced from the aperture 18 at the distal end of the tube 11.

In accordance with the invention, the distal end portion of the tube 11 has a conical tip generally designated 20 which smoothly merges with the cylindrical body of the tube 11. Preferably the apex of the conical tip 20 is centered on the axis of the cylindrical body of the tube 11 thus serving as a guidance point to uniformly distribute the frictional resistance encountered by the conical tip 20 when the tube 11 is inserted into the body cavity (not shown). As shown in FIGS. 1-4 and FIG. 7, the outer diameter of the tube 11 converges smoothly at the distal end portion of the tube defining a truncated cone 20 and the return lumen 13 opens at the truncated apex of the cone 18. Preferably, the conical tip 20 has a gradual taper. The conical tip 20, for example, has a length of at least approximately two diameters of the tube 11. Since the frictional resistance is uniformly distributed and the conical tip 20 smoothly merges with the body of the tube 11, insertion trauma and kinking are minimized.

The relatively small size of the return and inlet apertures 18, 19 further reduce insertion trauma, but they also impede fluid flow. Therefore, an additional group of holes or apertures generally designated 21 connect the return lumen 13 to the outer surface of the tube 11, and an additional group of holes or apertures 22 connect the inlet lumen 14 to the outer surface of the tube 11. Viewed from the side, the holes 21, 22 are seen to have elliptical margins. In particular the return holes or apertures 21 are axially disposed between the base of the conical tip 20 and the inlet aperture 19 at the distal end of the inlet lumen 14. The additional inlet holes or apertures 22 are axially disposed between the inlet aperture 19 and the proximal end of the tube 11. The return holes 21 and the inlet holes 22 are further disposed circumferentially on opposite sides of the divider 12. Thus, there is axial as well as circumferential separation of the inlets and outlets for fluid circulation.

In accordance with another aspect of the invention specifically shown in FIG. 7, the conical tip generally designated 20 is formed with a relative concentration of material 23 to stiffen the tip 20. This stiffening aids penetration of the tip 20 into the body cavity (not shown) and also aids the dilation of soft tissue such as veins. As shown in FIG. 7, the inlet lumen 14 terminates at the inlet aperture 19 and in place of the inlet lumen the relative concentration of material 23 extends axially from the aperture 19 to the distal end of the tube 11 at the truncated apex of the conical tip 20. Also, the wall thickness of the conical tip 20, the return lumen 13 and the aperture 18 are all concentric to the axis of the conical tip.

It is readily apparent to persons of ordinary skill in the art that the tip 20 as shown in FIG. 7 is easily formed from thermo-plastic material. The tip 20 molding the relative concentration of material 23 is easily molded and bonded or is integrally formed from the cylindrical tube 11 by the use of internal and external mandrels and the application of heat by any number of conventional means such as RF forming, thermal forming, or infrared forming.

For use in hemodialysis, the smooth bore double lumen catheter 10 is introduced in the direction of blood flow in a large vein over a hypodermic needle or Seldinger's guide wire, or through a sheath as is conventional. The side holes 19 and 22 on the blood inlet lumen 14 draw the blood for processing and the processed blood is returned through the return lumen 13 and out through the holes 18, 21 to return the blood upstream into circulation. As was described above, the geometrical properties of the smooth bore double lumen catheter as shown in the drawing figures insure that insertion trauma, kinking, and the possibility of clotting are minimized during hemodialysis.

What is claimed is:

1. A double lumen catheter comprising an elongated unitary cylindrical tube having a longitudinal planar septum, of one-piece construction with said tube, said septum dividing the interior of said tube into first and second lumens, the proximal end of said cylindrical tube connecting to two separate tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said cylindrical tube to an opening at the distal end of said cylindrical tube, and the second lumen extending from the proximal end of said cylindrical tube to at least one opening in the side of the cylindrical surface of said cylindrical tube, said opening to said second lumen being axially spaced from the distal end of said cylindrical tube,

said cylindrical tube having at its distal end a smooth conical tapered tip that smoothly merges with the

cylindrical surface of said cylindrical tube around the entire circumference of said tube, said first lumen and the internal wall thereof formed by said septum extending continuously through said conical tapered tip, and having a uniform diameter along its entire length from its proximal end to said conical tapered tip.

2. The double lumen catheter as claimed in claim 1, wherein the cylindrical surface of said cylindrical tube includes at least one side hole exposing said second lumen that is axially spaced between the opening to said second lumen and the proximal end of said cylindrical tube and is circumferentially disposed on the same side of the cylindrical tube as the opening to said second lumen.

3. The double lumen catheter as claimed in claim 1, wherein said conical tapered tip comprises a concentration of material substantially exceeding the concentration of material in the cylindrical body of said cylindrical tube.

4. The double lumen catheter as claimed in claim 1, wherein said cylindrical tube comprises a relative concentration of material extending axially from said opening in the side of said cylindrical surface of said cylindrical tube to the distal end of said cylindrical tube.

5. The double lumen catheter as claimed in claim 1, wherein said second lumen terminates at said opening in the side of said cylindrical surface of said cylindrical tube, and a relative concentration of material extends axially from said opening in the side of said cylindrical surface of said cylindrical tube to the distal end of said cylindrical tube.

6. The double lumen catheter as claimed in claim 1, wherein the apex of said conical tip is substantially aligned with the axis of said cylindrical tube.

7. The double lumen catheter as claimed in claim 1, wherein the length of said conical tip is at least approximately two diameters of said cylindrical tube.

8. The double lumen catheter as claimed in claim 1, wherein the first and second lumens are semicircular.

9. The double lumen catheter as claimed in claim 1, wherein the proximal end of said cylindrical tube is connected to said separate tubes by a connector including a sleeve coaxial with said cylindrical tube at the junction of the coaxial tube and the connector.

10. A double lumen catheter as claimed in claim 1, wherein the opening at the distal end of said cylindrical tube is eccentric with respect to the axis of the conical tapered tip.

11. The double lumen catheter as claimed in claim 1, wherein the wall thickness of the conical tapered tip is eccentric with respect to the axis of the conical tapered tip.

12. A double lumen catheter comprising an elongated cylindrical tube including a planar axial divider bisecting said cylindrical tube into first and second lumens, the proximal end of said cylindrical tube connecting two separate tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said cylindrical tube to a first opening at the distal end of said cylindrical tube, the second lumen extending from the proximal end of said cylindrical tube to a second opening in the side of the cylindrical surface of said cylindrical tube, said second lumen terminating at said second opening and a relative concentration of material extending axially from the second opening to the distal end of said cylindrical tube, the distal end of said cylindrical tube having a smooth conical tapered tip that smoothly merges with the cylindrical surface of said cylindrical tube, the cylindrical surface of said cylindrical tube having at least one side hole exposing said first lumen axially spaced between said second opening and said conical tapered tip and circumferentially disposed on the opposite side of said cylindrical tube as said second opening, and the cylindrical surface of said cylindrical tube having at least one side hole exposing said second lumen axially spaced between said second opening and the proximal end of said cylindrical tube and circumferentially disposed on the same side of said cylindrical tube as said second opening.

13. The double lumen catheter as claimed in claim 12, wherein the apex of said conical tip is substantially aligned with the axis of said cylindrical tube.

14. The double lumen catheter as claimed in claim 12, wherein the length of said conical tip is at least approximately two diameters of said cylindrical tube.

15. The double lumen catheter as claimed in claim 12, wherein the first opening in the distal end of said cylindrical tube is eccentric with respect to the axis of the conical tapered tip.

16. The double lumen catheter as claimed in claim 12, wherein the wall thickness of the conical tapered tip is eccentric with respect to the axis of the conical tapered tip.

17. The double lumen catheter as claimed in claim 12, wherein the first and second lumens are semicircular.

18. The double lumen catheter as claimed in claim 12, wherein the proximal end of said cylindrical tube is connected to said separate tubes by a connector including a sleeve coaxial with said cylindrical tube at the junction of the connector and said cylindrical tube.

19. A double lumen catheter comprising an elongated unitary tube including an integral septum extending axially along the entire length of the tube and dividing the interior of said tube into a first and a second lumen, the outer circumference of said tube converging smoothly at the distal end portion of said tube defining a truncated cone, the first lumen opening at the truncated apex of said cone, and the second lumen being shorter in axial length than the first lumen and opening upon the outer circumference of said tube, said tube having a uniform diameter from its distal end portion to proximally beyond the opening of the second lumen upon the outer circumference.

20. The double lumen catheter as claimed in claim 19, wherein the first lumen is eccentric to the axis of said cone.

21. The double lumen catheter as claimed in claim 19, wherein said second lumen opens upon the outer circumference of said tube at a plurality of openings having scalloped margins.

22. The double lumen catheter as claimed in claim 19, wherein said second lumen opens upon the outer circumference of said tube at a plurality of holes.

23. The double lumen catheter as claimed in claim 19, wherein said first and second lumens are semicircular.

24. The double lumen catheter as claimed in claim 19, further comprising a branching connector at the proximal end of said tube including sleeve coaxial with said tube at the junction of said tube and the branching connector.

25. A double lumen catheter comprising an elongated unitary cylindrical tube having a longitudinal planar septum of one-piece construction with said tube, said septum dividing the interior of the tube into first and

second lumens, the proximal end of said cylindrical tube connecting to two separate tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said cylindrical tube to an opening at the distal end of said cylindrical tube, and the second lumen extending from the proximal end of said cylindrical tube to at least one opening in the side of the cylindrical surface of said cylindrical tube, said opening to said second lumen being axially spaced from the distal end of said cylindrical tube,

said cylindrical tube having at its distal end a smooth conical tapered tip that smoothly merges with the cylindrical surface of said cylindrical tube around the entire circumference of said tube, said first lumen and the proximal wall thereof formed by said septum extending continuously through said conical tapered tip, and

wherein said cylindrical tube comprises a relative concentration of material extending axially from said opening in the side of said cylindrical surface of said cylindrical tube to the distal end of said cylindrical tube.

* * * * *

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United States Patent [19]

Mahurkar

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[45] Date of Patent: Jan. 23, 1990

[54] DUAL-LUMEN CATHETER-CONNECTING SYSTEM

[76] Inventor: Sakharam D. Mahurkar, 6271 N. Sheridan Rd., Suite 1112, Chicago, Ill. 60660

[21] Appl. No.: 194,143

[22] Filed: May 16, 1988

[51] Int. Cl.[4] A61M 25/00

[52] U.S. Cl. 604/43; 604/55; 604/283; 604/174

[58] Field of Search 604/280, 283, 43-45, 604/244, 281, 282, 174, 179

[56] References Cited

U.S. PATENT DOCUMENTS

3,278,855	6/1966	Hoggan et al.	604/281
3,812,851	5/1974	Rudolphus	604/179
4,557,261	12/1985	Rugheimer	604/283
4,626,240	12/1986	Edelman et al.	604/43
4,643,711	2/1987	Bates	604/43
4,682,978	7/1987	Martin	604/281

Primary Examiner—Stephen C. Pellegrino
Attorney, Agent, or Firm—Stephen G. Rudisill

[57] ABSTRACT

A dual-lumen catheter assembly comprising a dual-lumen catheter, a Y connector having one end fastened to the proximal end of the catheter, and a pair of extension tubes each having one end fastened to the opposite end of the connector from the catheter, each of the extension tubes being bent back toward the distal end of the catheter, extending along opposite sides of the connector.

53 Claims, 5 Drawing Sheets

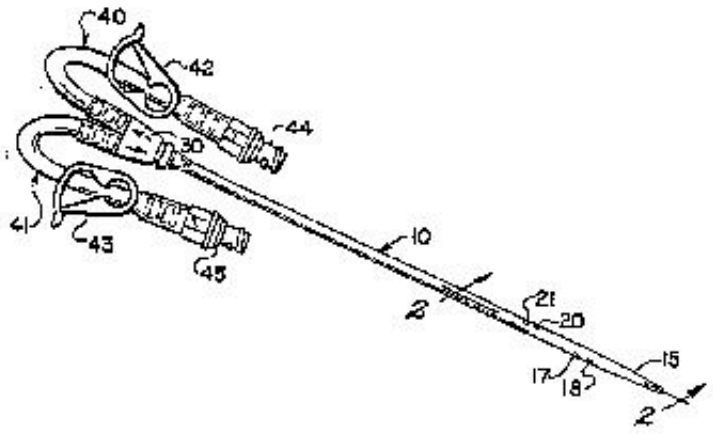

EXHIBIT B

EXHIBIT B

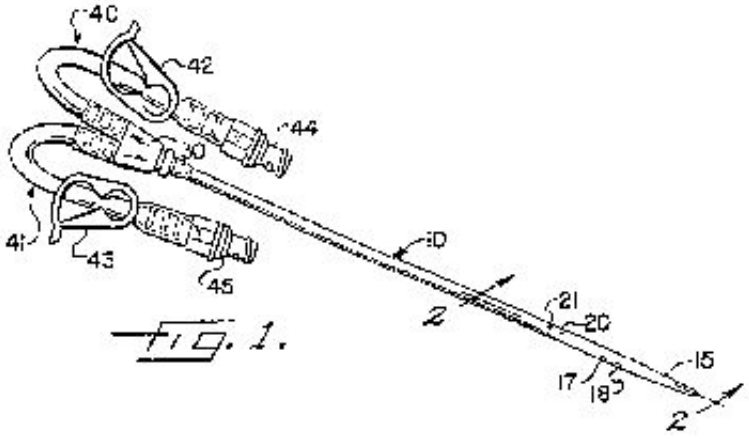

Fig. 1.

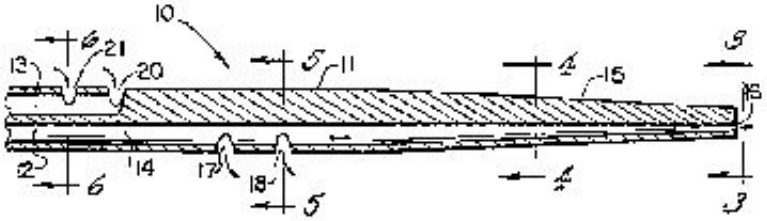

Fig. 2.

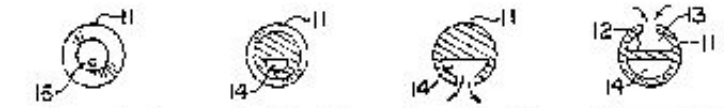

Fig. 3. Fig. 4. Fig. 5. Fig. 6.

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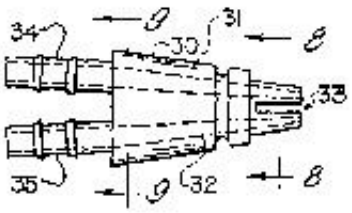

Fig. 7.

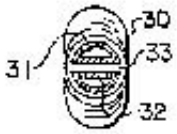

Fig. 8.

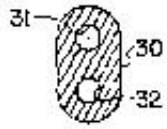

Fig. 9.

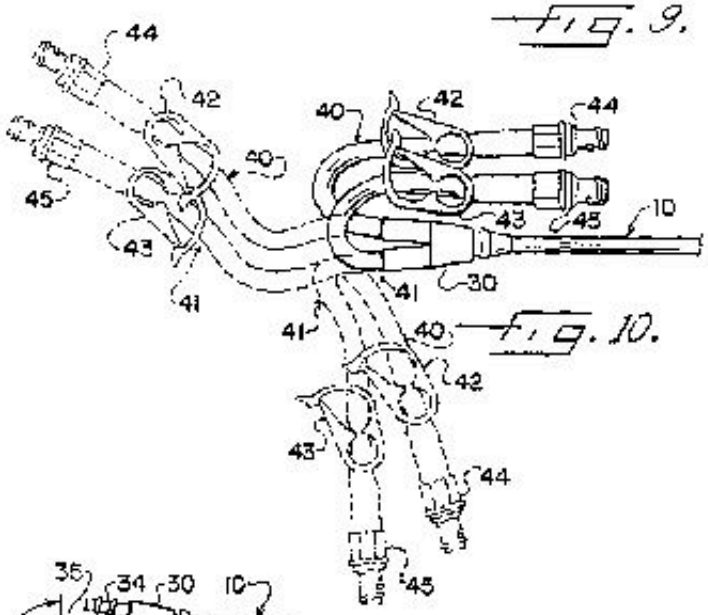

Fig. 10.

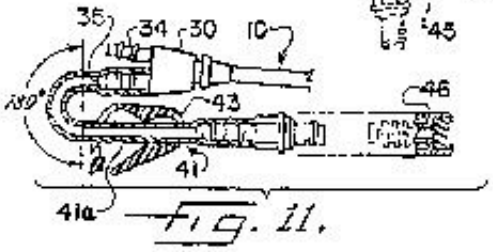

Fig. 11.

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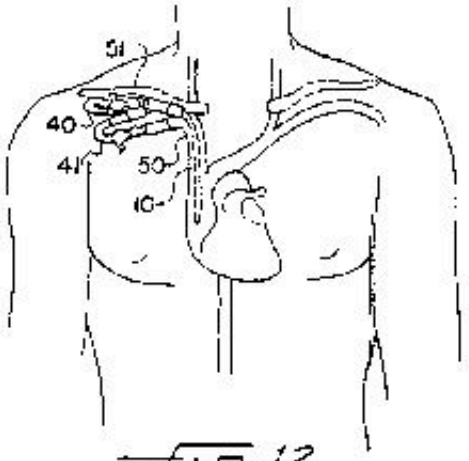

Fig. 12.

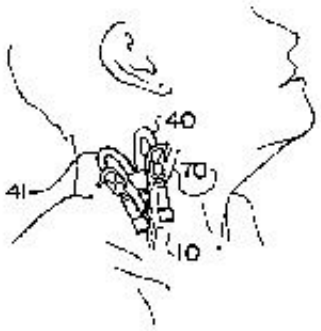

Fig. 13.

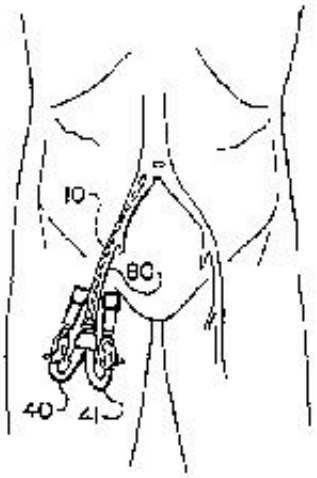

Fig. 14.

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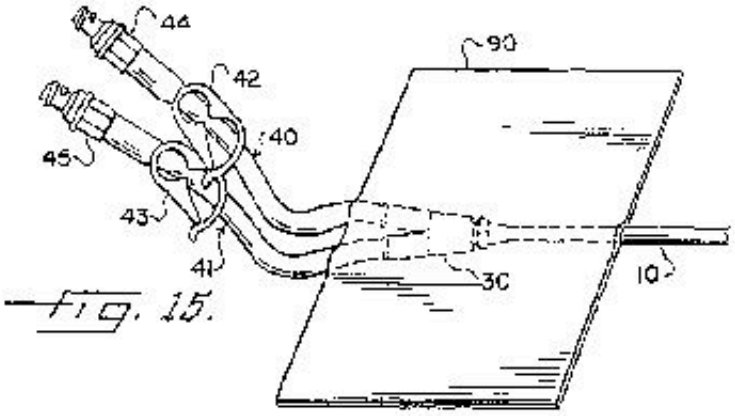

fig. 15.

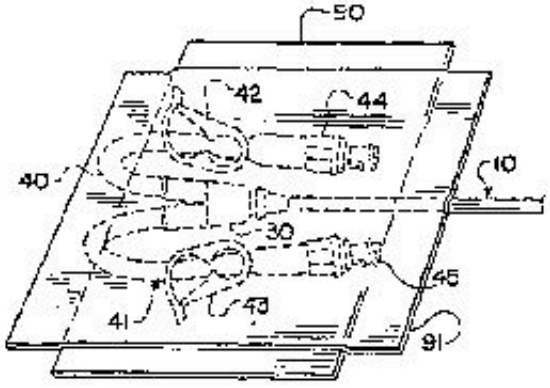

fig. 16.

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DUAL-LUMEN CATHETER-CONNECTING SYSTEM

FIELD OF THE INVENTION

The present invention relates generally to extracorporeal blood treatment systems and, more particularly, to an improved method and apparatus for connecting a dual-lumen catheter to the long flexible tubes which carry blood in both directions between the catheter and an extracorporeal blood treatment unit. This invention is particularly concerned with such a method and apparatus which permits the catheter to be positioned in convenient anatomical sites during the periods between successive treatments to avoid patient discomfort and accidental displacement of the catheter, and to facilitate sterile attachment of the catheter to the patient during such periods.

BACKGROUND OF THE INVENTION

Dual-lumen catheters have come into widespread use for extracorporeal blood purification procedures such as hemodialysis. Blood is withdrawn from the patient through one of the lumens of the catheter and supplied to a hemodialysis unit where the blood is purified, and the resulting purified blood is then returned to the patient through the other lumen of the catheter. Examples of such catheters are shown in U.S. Pat. Nos. 4,134,402; 4,583,968; and 4,692,978.

Although these catheters were originally intended for acute hemodialysis treatments, the catheters have proven to be so satisfactory that they are typically allowed to remain in patients for several weeks, and sometimes for several months. The catheters are used for the hemodialysis treatments that such patients receive approximately every three days, and during the interdialytic periods the catheter remains inserted in and attached to the patient.

Dual-lumen hemodialysis catheters are normally supplied with certain auxiliary components permanently pre-attached to the catheter. These auxiliary components facilitate the connection of the two lumens of the catheter (which are extremely small within the catheter) to a pair of long flexible tubes which carry blood to and from the hemodialysis unit. The auxiliary components include a Y-shaped hub which receives the proximal end of the catheter at one end of the hub, and a pair of extension tubes which are fastened to the opposite end of the hub and carry a pair of clamps, female luer fittings for connection to male luer fittings on the long tubes leading to the hemodialysis unit, and a pair of caps (usually with injectable elastomeric ports) closing the openings of the luer fittings.

The hub and portions of the extension tubes affixed to the catheter are normally used to secure the catheter to the patient, by the use of sutures and by applying tape or an adhesive-coated bandage across the hub and/or the extension tubes and adhering the tape or bandage to the skin of the patient on opposite sides of the hub. Sometimes the hub forms either a suture groove or a suture web or "wing" to facilitate attachment to the patient by suturing. Because of the length of the extension tubes and the other auxiliary components, the extracorporeal part of the catheter assembly usually extends beyond the patient's body. As a result, the catheter is constantly disturbed by movements of the patient and/or people and equipment around the patient, or by clothing which is periodically donned or removed by the patient.

It is not unusual for such movements to cause the catheter to become dislodged entirely from the patient. Even when the catheter is not dislodged, continual movement of the catheter within the vein causes discomfort and pain to the patient, and can lead to damage to the vein in which the catheter is inserted.

For example, when the catheter is inserted in a jugular vein, the extension tubes normally extend upwardly along the neck and ear of the patient. This not only makes it difficult to attach the catheter to the patient (sometimes the hub or extension tubes are taped to the ear or even around the entire neck or head of the patient), but also places both the hub and the extension tubes in the direct path of movement of the patient's head. When the catheter is inserted into a subclavian vein, which is located under the clavicle, the extension tubes typically project upwardly or outwardly beyond the shoulder of the patient.

Regardless of where the catheter is located on the patient's body, the weight of the long tubes leading to the dialysis unit, which typically have a larger cross section than the extension tubes, often exerts pulling forces on the extension tubes and the catheter which of course tends to withdraw the catheter from the patient's body. These forces are also applied to the sutures, causing discomfort and pain to the patient, and can cause the catheter to pivot back and forth within the vein, thereby irritating the walls of the vein. Such catheter movements can also cause suction forces to be exerted on the vein walls.

SUMMARY OF THE INVENTION

It is a primary object of the present invention to provide an improved dual-lumen catheter-connecting system which permits the catheter to remain relatively stable during the entire time the catheter remains inserted in the patient, even during long-term use of the catheter extending over numerous extracorporeal blood treatments. In this connection, related objects of the invention are to provide such a catheter-connecting system which significantly improves the comfort level of the patient in whom the catheter is inserted, and which greatly reduces the risk of vessel damage.

A more specific object of the invention is to provide an improved dual lumen catheter system which enables the catheter to be secured to the body of the patient in natural anatomical depressions, or fossa, where the extracorporeal portions of the catheter assembly are shielded by the patient's body. In these regions the catheter is not easily disturbed by movements of the patient or by movement of people and articles around the patient, regardless of the particular vein into which the catheter is inserted. In this connection, a related object is to provide such a system which facilitates the donning and removal of clothing by the patient, and which enables ambulatory patients to wear normal clothing, without any unsightly or embarrassing projections, between successive extracorporeal blood treatments.

Another important object of this invention is to provide an improved hemodialysis catheter-connecting system which facilitates connection of the catheter and its attached auxiliary components to the long flexible tubes which lead to the dialysis unit, regardless of where the dialysis unit is positioned relative to the patient.

One specific object of the invention is to eliminate the need to attach the auxiliary components of a dual-lumen catheter, to the neck, ears or head of the patient when the catheter is inserted in a jugular vein, and which discourages the use of bandages or tape encircling the neck of the patient.

A further object of the invention is to reduce the area that must be covered with a bandage around the proximal end of the catheter in order to maintain sterile conditions around the access site.

Yet another object of the invention is to facilitate connection of a dual-lumen hemodialysis catheter to a hemodialysis unit located anywhere around the patient.

A still further object of the invention is to provide an improved catheter-connecting system which to a large extent isolates the catheter from retracting forces and bending moments applied to the extension tubes, thereby reducing movement of the catheter tip within the vein and consequently reducing irritation and suction forces on the vein walls. A related specific object is to eliminate any projection of the auxiliary components of the catheter beyond the extremity of the shoulder of the patient when the catheter is inserted into the subclavian vein of the patient.

It is another object of the invention to provide such a system which avoids kinking of the extension tubes and helps prevent collapse and maintain patency of the extension tubes.

A further object is to avoid the exertion of pulling forces, due to the weights of the dialysis tubes, on the catheter, and to reduce such forces on the sutures attaching the catheter assembly to the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages of the invention will become apparent upon reading the following detailed description and upon reference to the drawings in which:

FIG. 1 is a perspective view of a dual-lumen hemodialysis catheter assembly embodying the present invention;

FIG. 2 is an enlarged longitudinal section taken along a diameter of the distal portion of the catheter of FIG. 1, perpendicular to the septum inside the catheter, as generally illustrated by line 2—2 in FIG. 1;

FIG. 3 is an end elevation taken at the distal end of the catheter portion shown in FIG. 2 as illustrated by line 3—3 in FIG. 2;

FIG. 4 is a section taken generally along line 4—4 in FIG. 2;

FIG. 5 is a section taken generally along line 5—5 in FIG. 2;

FIG. 6 is a section taken generally along line 6—6 in FIG. 2;

FIG. 7 is a plan view of the Y-shaped hub of the catheter assembly of FIG. 1;

FIG. 8 is a section taken generally along line 8—8 in FIG. 7;

FIG. 9 is a section taken generally along line 9—9 in FIG. 7;

FIG. 10 is a fragmentary side elevation of the catheter assembly of FIG. 1, illustrating the extension tubes in three different positions;

FIG. 11 is a partial side elevation and partial sectional view of one of the extension tubes and the auxiliary components associated therewith in the catheter assembly of FIG. 1;

FIG. 12 is a diagrammatic view of a portion of a human body with the catheter of FIG. 1 inserted in a subclavian vein;

FIG. 13 is a diagrammatic view of a portion of a human body having the catheter of FIG. 1 inserted in a jugular vein;

FIG. 14 is a diagrammatic view of a portion of a human body having the catheter of FIG. 1 inserted in a femoral vein;

FIG. 15 is a perspective view of the first part of a two-part attachment system for the catheter assembly of FIG. 1;

FIG. 16 is a perspective view of a two-part attachment system for the catheter of FIG. 1, including the first part shown in FIG. 15;

FIG. 17 is a partial side elevation and partial sectional view of an alternative attachment system for the catheter of FIG. 1; and

FIG. 18 is a partial side elevation and partial sectional view of the attachment system shown in FIG. 17 with the catheter assembly in a closed condition.

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and will herein be described in detail. It should be understood, however, that it is not intended to limit the invention to the particular forms disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Turning now to the drawings and referring first to FIG. 1, there is shown a dual-lumen hemodialysis catheter 10 of the type described in Mahurkar U.S. Pat. No. 4,583,968, issued Apr. 22, 1986 for "Smooth Bore Double Lumen Catheter". This catheter 10 has a cylindrical body portion 11 which is hollow except for a flat, longitudinal, diametral septum 12 which divides the interior of the hollow cylinder into two parallel lumens 13 and 14, each having a D-shaped cross section (FIGS. 2 and 3). As illustrated by the arrows in FIG. 2, the lumen 13 is the blood-intake lumen, and the lumen 14 is the blood-return lumen.

At the distal end of the catheter, the exterior surface of the cylinder 11 merges into a smoothly tapered conical tip 15. On the inside, the blood return lumen 14 extends longitudinally all the way through the tip 15, bending slightly as it passes through the tip so that it opens at 16 near the center of the distal end of the conical tip, as can be seen in FIGS. 2 and 3. Within the tip 15, the cross sectional shape of the lumen 14 gradually changes from D-shaped at the proximal end of the tip 15 (see FIG. 5) to circular at the distal end of the tip (see FIG. 3). An intermediate configuration of the transition from D to circular is shown in the sectional view in FIG. 4.

In addition to the opening 16 at the distal end of the blood-return lumen 14, a pair of additional apertures 17 and 18 are formed in the side wall of the return lumen. These two apertures 17 and 18 are spaced longitudinally away from the distal opening 16 toward the proximal end of the catheter. These apertures ensure the flow of blood through the return lumen 14 even in situations where the distal opening 16 might become wholly or partially blocked.

In order to provide a longitudinal spacing between the distal openings of the two lumens 13 and 14, the blood intake lumen is terminated at an opening 20 in the side wall of the catheter. A second opening 21 spaced longitudinally from the opening 20 permits blood to enter the lumen 13 in the event of a blockage of the opening 20 against the wall of the vein into which the catheter 10 is inserted.

At the proximal end of the catheter 10, the two D-shaped lumens 13 and 14 open into a Y-shaped connector or hub 30 which forms two internal passageways 31 and 32 (see FIGS. 7-9) communicating with the proximal ends of the catheter lumens. As can be seen in FIGS. 7 and 8, the distal ends of the hub passageways 31 and 32 are D-shaped and are separated by a thin gap 33 for receiving the septum 12 of the catheter. The walls of the catheter lumens are expanded at the proximal end of the catheter to fit over the corresponding portions of the hub 30, as shown in FIG. 1, and the inside walls of the catheter lumens are preferably bonded to the mating walls of the hub 30. The passageways 31 and 32 then diverge from each other and assume a circular cross section (see FIG. 9) as they extend toward the proximal end of the hub, and they also increase in cross-sectional area, as can be seen in FIG. 7. At the proximal end of the hub 30, the hub passageways 31 and 32 open into a pair of ferrules 34 and 35 formed as integral parts of the hub.

To facilitate connection of the catheter hub 30 to the conventional tubes leading to a dialysis unit, and also to accommodate a pair of clamps for opening and closing the blood intake and return passageways, a pair of extension tubes 40 and 41 are attached to the ferrules 34 and 35 on the proximal end of the hub 30. These extension tubes 40 and 41 are typically formed of a polymeric material such as silicone, and are long enough to receive a pair of conventional clamps 42 and 43 for opening and closing the respective tubes. The clamps 42 and 43 serve as on-off valves or flow control devices for controlling the flow of blood between the catheter and the dialysis unit.

The distal ends of the extension tubes 40 and 41 are permanently attached to the Y connector, and the proximal ends of the tubes are permanently bonded to a pair of female luer fittings 44 and 45 which match the male luer fittings conventionally provided on the ends of the tubes leading to the dialysis unit. The mating luer fittings serve as coupling means for coupling the proximal ends of the extension tubes to the flexible tubes leading to the extracorporeal blood treatment unit. The extension tubes 40 and 41 are relatively soft and flexible, so that they can be easily manipulated and also easily closed by the pressure of the clamps 42 and 43.

In accordance with one important aspect of the present invention, the extension tubes are bent back toward the distal end of the catheter, preferably extending along the sides of the catheter and the Y-shaped hub. By providing these U-bends in the extension tubes, the auxiliary connecting elements attached to the proximal end of the catheter can be accommodated in a small area around the access site on the patient's body. Consequently, the entire connecting assembly for the catheter, including the luer fittings on the proximal ends of the extension tubes, can be located on a protected portion of the patient's body. There are no projections to interfere with movements of the patient, or with the movement of people and articles around the patient. It is also easy for the patient to don and remove clothing, and normal clothing can be worn by the patient during interdialytic periods without any unsightly or embarrassing projecting portions of the catheter assembly.

Perhaps even more importantly, any forces exerted on the proximal ends of the extension tubes tend to move the catheter in a direction opposite that of the applied force. Thus, when pulling forces are exerted on the extension tubes by the long and relatively heavy tubes leading to the dialysis unit, for example, these forces tend to push the catheter into the patient to hold it in place, rather than withdrawing the catheter. Consequently, the risk of accidental dislodgement of the catheter is greatly reduced, as is the risk of vein irritation and damage.

In the particular embodiment illustrated in the drawings the U-bend in each extension tube 40 and 41 begins at a point just slightly beyond the proximal end of the hub ferrule 34 or 35 (see FIG. 11). The bend is exactly 180°, and terminates in a straight length of tubing 40a or 41a which is long enough to receive one of the clamps 42 and 43 and the stem of the luer fitting 44 or 45 and its cap 46 (see FIG. 11).

In accordance with one particular aspect of the invention, the U bends are permanently formed in the extension tubes 40 and 41. That is, both the overall shape of the bend and the size of the interior passageway of the bend are set or "memorized" in the extension tube so that the tube always returns to that configuration. The U-bends are still flexible but are substantially stiffer than the straight end portions of the tubes, as a result of which any forces applied to the more flexible end portions of the tubes tend to simply pivot those flexible end portions about the relatively stiff bent portions. Consequently, the catheter is to a large extent isolated from bending moments applied to the end portions of the extension tubes. This greatly reduces pivoting and tilting movements of the catheter within the vein, thereby further reducing irritation of the vein walls and the attendant risk of venous damage.

The relatively stiff U-bends also form a fulcrum about which the proximal portions of extension tubes can be turned to facilitate connection to a dialysis unit located anywhere within a 360° circle around the patient. This flexibility of the catheter assembly is illustrated in FIG. 10, which shows the extension tubes bent laterally to one side of the catheter in solid lines, to the other side in dashed lines, and in a direction away from the catheter in phantom lines.

With certain silicones and other polymeric materials, the extension tubes 40 and 41 may be set in the desired size and shape by simply heating each tube while holding it in the desired size and shape. One simple and effective way to accomplish this is to slide the extension tube over a U-shaped wire or rod which defines the radius of the desired bend and also the size of the interior passageway to be maintained within the bend. The curved portion of the tube, with the wire still in place, is then dipped in a liquid heated to a temperature sufficient to set, i.e., effect cross linking of, the polymer. Alternatively, the bent portions of the extension tubes can be molded or otherwise formed from a polymer that has a greater durometer than the straight sections of the tubes.

FIG. 12 illustrates the catheter of FIG. 1 inserted in a subclavian vein 50 of a patient. It can be seen that the access site for the catheter 10 is located adjacent the clavicle 51 of the patient, and the catheter is inserted in a direction generally parallel to the clavicle 51. Thus,

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the distal portions of the extension tubes 40 and 41 connected to the Y-shaped hub 30 extend outwardly from the hub 30 toward the outer extremity of the shoulder of the patient. Because of the U-bends in the extension tubes, however, the extension tubes 40 and 41 curve back toward the center of the patient's body before they reach the outer extremity of the shoulder. The luer connections to the long tubes leading to the dialysis unit are consequently located close to the access site. As a result, the entire catheter assembly is nestled in a relatively small region around the access site in the infraclavicular fossa, where the catheter and its auxiliary components are sheltered by the body of the patient from people and articles moving around the patient. No portion of the catheter assembly projects beyond the body of the patient, nor interferes with movements of the patient. When the tubes leading to the dialysis unit are disconnected from the luer fittings on the catheter assembly, an ambulatory patient can move freely about with little concern about snagging the catheter assembly on clothing or other articles.

FIG. 13 illustrates a patient having the catheter assembly of FIG. 1 inserted in a jugular vein 70. It can be seen that the access site to the jugular vein 70 is located at the base of the neck of the patient, and the catheter 10 is inserted downwardly into the jugular vein. Consequently, the straight distal portions of the extension tubes 40 and 41 extend upwardly along the lower portion of the patient's neck. Because of the presence of the U-bends in the extension tubes, the straight proximal portions of the extension tubes 40 and 41 bend back down along the lower portion of the patient's neck so that the luer fittings are located near the access site. Here again, the entire catheter assembly ends up being located in a compact area where it is well protected in the cervical triangle of the patient's body.

FIG. 14 illustrates a patient having the catheter assembly of FIG. 1 inserted in a femoral vein 80. The catheter is inserted upwardly into the femoral vein 80 along the patient's thigh. The distal ends of the extension tubes 40 and 41 then extend downwardly along the thigh but, because of the presence of the U-bends in the extension tubes, the proximal ends of the tubes curve upwardly along the thigh. Consequently, the catheter assembly does not interfere with surrounding organs and leg movements of the patient. Moreover, the catheter assembly remains snugly attached to the patient in the well protected femoral triangle region of the body.

FIGS. 15 and 16 illustrate a preferred two-tier arrangement for attaching the catheter assembly to the patient. In this arrangement, the access site, the hub 30, and the straight distal portions of the extension tubes 40 and 41 are attached to the patient by an adhesive bandage 90 as illustrated in FIG. 15. The straight proximal portions of the extension tubes, including the clamps and luer fittings carried thereby, are then placed on top of the bandage 90 and fastened by a second bandage 91 so that they are held securely in place on the top surface of the bandage 90. The bandage 90 is thus used to protect the patient from abrasion due to rubbing of the clamps and/or the luer fittings on the skin of the patient, and also isolates the Y connector from the movements of the extension tubes during dialysis.

FIGS. 17 and 18 illustrate an alternative attachment technique which also seals the open ends of the luer fittings on the catheter assembly. As illustrated in FIG. 17, a first length of tape 100 is applied along one side of the catheter assembly, with the U-bends in the extension tubes straightened out. Then when the extension tubes are allowed to relax, returning the extension tubes to their normal U-shaped configuration, the tape 100 bends on itself to hold the catheter assembly firmly in position in its relaxed condition. Next, a second length of tape 101 is applied over the catheter assembly, with the portion of the tape 101 that extends beyond the luer fittings adhering to the first tape 100. This forms a relatively tight seal around the open ends of the luer fittings, preventing the entry of bacteria into the catheter assembly. The second length of tape 101 is adhered to the body of the patient to hold the entire catheter assembly securely in place in the desired location on the patient's body.

While the invention has been described with specific reference to the use of permanently bent extension tubes, the curved passageways provided by those extension tubes may instead be formed by a unitary connecting member fastened to the proximal end of the dual-lumen catheter. More specifically, the unitary connecting member may form two internal U-shaped passageways, each of which is in communication with one of the lumens of the catheter. The other ends of the passageways may terminate in a pair of integral ferrules for direct connection to a pair of tubes leading to the dialysis unit, or the passageways may lead into a pair of straight extension tubes carrying the conventional clamps and luer fittings. Because the internal passageways are U-shaped, curving back toward the distal end of the catheter, any forces applied to the unitary connecting member by tubes leading to the dialysis unit will tend to move the catheter in a direction opposite that of the applied forces. Consequently, pulling forces exerted on the connecting member will tend to hold an inserted catheter in place rather than withdrawing it.

I claim:

1. A dual-lumen catheter assembly comprising:

a dual-lumen catheter having a distal end and a proximal end,

flow diversion means having one end fastened to the proximal end of said catheter, and

a pair of flexible extension tubes each having one end fastened to the opposite end of said flow diversion means from said catheter, each of said extension tubes being bent back toward the distal end of said catheter to form a bend having a predetermined shape, each bend being adapted to flex and deform from said predetermined shape in response to an external force and being adapted to return to said predetermined shape in response to removal of said external force.

2. The catheter assembly of claim 1 wherein said extension tubes, including the bends therein, are flexible.

3. The catheter assembly of claim 1 wherein the bent extension tubes and the flow diversion means lie in substantially the same plane.

4. The catheter assembly of claim 1 which includes a pair of luer fittings fastened to the proximal ends of said extension tubes, and a closure cap on each of said luer fittings.

5. The catheter assembly of claim 1 wherein said connector includes a pair of ferrules on said opposite end thereof, and said extension tubes are fastened to said ferrules.

6. The catheter assembly of claim 1 which includes flow control means on each of said extension tubes, on the proximal sides of said bends in said tubes.

7. The catheter assembly of claim 1 wherein said flow diversion means includes a pair of internal passageways communicating with the dual lumens of said catheter at said one end of said flow diversion means and with said extension tubes at said opposite end of said flow diversion means.

8. The catheter assembly of claim 1 wherein the bends in said extension tubes are generally U-shaped.

9. The catheter assembly of claim 1 wherein said dual-lumen catheter comprises a cylindrical body portion having an internal longitudinal septum forming a pair of elongated lumens having D-shaped cross sections, the distal end of said body portion terminating in a smooth conical tapered tip, one of said lumens extending longitudinally through said tip, and the other lumen terminating at an opening formed in the side wall of said catheter proximally of the distal end of said tip.

10. A blood treatment system comprising

a dual-lumen catheter having a distal end and a proximal end,

flow diversion means having one end fastened to the proximal end of said catheter,

a pair of flexible extension tubes each having one end fastened to the opposite end of said flow diversion means from said catheter, each of said extension tubes being bent back toward the distal end of said catheter to form a bend having a predetermined shape, each bend being adapted to flex and deform from said predetermined shape in response to an external force and being adapted to return to said predetermined shape in response to removal of said external force,

a blood treatment unit for receiving blood withdrawn from a patient through one of the lumens of said catheter, purifying the withdrawn blood, and returning the purified blood to the patient through the other lumen of said catheter,

a pair of flexible tubes connecting said extension tubes to said blood treatment unit,

flow control means for controlling the flow of blood between said catheter and said blood treatment unit, and

coupling means for coupling the proximal ends of said extension tubes to said flexible tubes.

11. The system of claim 10 wherein said catheter is inserted into a patient and which includes a bandage fastening said flow diversion means to the skin of the patient, with the portions of said extension tubes on the proximal sides of said bends positioned on top of said bandage.

12. The system of claim 11 which includes means fastening to the top of said bandage the portions of said extension tubes on the proximal sides of said bends.

13. The system of claim 11 which includes flow control means and luer fittings installed, said extension tubes on the proximal sides of said bends.

14. The system of claim 10 wherein said extension tubes, including said bends, are flexible.

15. The system of claim 11 wherein the bent extension tubes and said flow diversion means lie in substantially the same plane.

16. The system of claim 10 which includes a pair of luer fittings fastened to the proximal ends of said extension tubes, and a closure cap on each of said luer fittings.

17. The system of claim 10 wherein said connector includes a pair of ferrules on said opposite end thereof, and said extension tubes are fastened to said ferrules.

18. The system of claim 10 which includes flow control means on each of said extension tubes, on the proximal sides of said bends in said tubes.

19. The system of claim 10 wherein said flow diversion means forms a pair of internal passageways communicating with the dual lumens of said catheter at said one end of the connector and with said extension tubes at said opposite end of the connector.

20. The system of claim 10 wherein the bends in said extension tubes are generally U-shaped.

21. A method of preparing a patient for extracorporeal blood treatment comprising the steps of inserting into a vein selected from the group consisting of the jugular, subclavian and femoral veins of the patient, the distal end portion of a dual-lumen catheter assembly having

flow diversion means having one end fastened to the proximal end of said catheter,

a pair of flexible extension tubes each having one end fastened to the opposite end of said flow diversion means from said catheter, each of said extension tubes being bent back toward the distal end of said catheter and extending alongside said flow diversion means to form a bend having a predetermined shape, each bend being adapted to flex and deform from said predetermined shape in response to an external force and being adapted to return to said predetermined shape in response to removal of said external force,

flow control means for controlling the flow of blood between said dual-lumen catheter and an extracorporeal blood treatment unit, and

coupling means for coupling said extension tubes to said blood treatment unit, and

taping said flow diversion means and extension tubes to the skin of the patient.

22. The method of claim 21 wherein said flow diversion means and extension tubes are attached to the skin of the patient by a bandage, and the portions of said extension tubes on the proximal sides of said bends are positioned on top of said bandage.

23. The method of claim 22 which includes the step of fastening to the top of said bandage the portions of said extension tubes on proximal sides of said bends.

24. The method of claim 22 wherein said extension tubes have flow control means and luer fittings installed on the proximal sides of said bends.

25. The method of claim 21 wherein said extension tubes, including said bends, are flexible.

26. The method of claim 21 wherein the bent extension tubes and said flow diversion means lie in substantially the same plane.

27. The method of claim 21 wherein said extension tubes have a pair of luer fittings fastened to the proximal ends thereof, and a closure cap on each of said luer fittings.

28. The method of claim 21 wherein said connector includes a pair of ferrules on said opposite end thereof, and said extension tubes are fastened to said ferrules.

29. The method of claim 21 wherein said extension tubes have flow control means installed on the proximal sides of said bends in said tubes.

30. The method of claim 21 wherein said flow diversion means forms a pair of internal passageways communicating with the dual lumens of said catheter at said one end of said flow diversion means and with said extension tubes at said opposite end of said flow diversion means.

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31. The method of claim 21 wherein the bends in said extension tubes are generally U-shaped.

32. The method of claim 26 wherein the next extension tubes are attached to the skin of the patient by a first tape extending generally in the direction of the longitudinal axis of the catheter and extending beyond the bends in the extension tubes at one end and beyond the catheter insertion point at the other end.

33. The method of claim 32 which includes a second tape covering the best extension tube and said first tape and attached to the skin of the patient at opposite ends of the second tape.

34. A dual-lumen catheter assembly comprising

a dual-lumen catheter, and

connecting means attached to the proximal end of said catheter and forming a pair of internal passageways which communicate at one end thereof with the dual lumens in said catheter, said passageways curving back toward the distal end of said catheter so that forces exerted on said connecting means at the other ends of said passageways will tend to move said catheter in a direction opposite that of said exerted forces.

35. The catheter assembly of claim 34 wherein said connecting means comprises a connector fastened to the proximal end of said catheter, and a pair of extension tubes fastened to said connector, said connector forming a pair of internal passageways connecting each of the catheter lumens to one of said extension tubes, and said extension tubes forming said curved passageways.

36. The catheter assembly of claim 34 wherein each of said curved passageways is U-shaped.

37. The catheter assembly of claim 34 wherein said dual-lumen catheter comprises a cylindrical body portion having an internal longitudinal septum forming a pair of elongated lumens having D-shaped cross sections, the distal end of said body portion terminating in a smooth conical tapered tip, one of said lumens extending longitudinally through said tip, and the other lumen terminating at an opening formed in the side wall of said catheter proximally of the distal end of said tip.

38. A blood treatment system comprising

a dual-lumen catheter,

connecting means attached to the proximal end of said catheter and forming a pair of internal passageways which communicate at one end thereof with the dual lumens in said catheter, said passageways curving back toward the distal end of said catheter so that forces exerted on said connecting means at the other ends of said passageways will tend to move said catheter in a direction opposite that of said exerted forces,

a blood treatment unit for receiving blood withdrawn from a patient through one of the lumens of said catheter, purifying the withdrawn blood, and returning the purified blood to the patient through the other lumen of said catheter, and

a pair of flexible tubes connecting said extension tubes to said blood treatment unit.

39. The system of claim 38 wherein said connecting means comprises a connector fastened to the proximal end of said catheter, and a pair of extension tubes fastened to said connector, said connector forming a pair of internal passageways connecting each of the catheter lumens to one of said extension tubes, and said extension tubes forming said curved passageways.

40. The system of claim 38 wherein each of said curved passageways is U-shaped.

41. The system of claim 38 wherein said dual-lumen catheter comprises a cylindrical body portion having an internal longitudinal septum forming a pair of elongated lumens having D-shaped cross sections, the distal end of said body portion terminating in a smooth conical tapered tip, one of said lumens extending longitudinally through said tip, and the other lumen terminating at an opening formed in the side wall of said catheter proximally of the distal end of said tip.

42. A method of preparing a patient for extracorporeal blood treatment comprising the steps of

inserting into a vein selected from the group consisting of the jugular, subclavian and femoral veins of the patient, the distal end portion of a dual-lumen catheter having connecting means attached to the proximal end of said catheter and forming a pair of internal passageways which communicate at one end thereof with the dual lumens in said catheter, said passageways curving back toward the distal end of said catheter so that forces exerted on said connecting means at the other ends of said passageways will tend to move said catheter in a direction opposite that of said exerted forces, and

taping said connector and extension tubes to the skin of the patient.

43. The method of claim 42 wherein said connector and extension tubes are attached to the skin of the patient by a bandage, and the portions of said extension tubes on the proximal sides of said bends are positioned on top of said bandage.

44. The method of claim 43 which includes the step of fastening to the top of said bandage the portions of said extension tubes on the proximal sides of said bends.

45. The method of claim 43 wherein said extension tubes have flow control means and luer fittings installed on the proximal sides of said bends.

46. The method of claim 42 wherein the bends in said extension tubes are permanently set in said tubes.

47. The method of claim 47 wherein said extension tubes, including said bends, are flexible.

48. The method of claim 42 wherein the bent extension tubes and the connector lie in substantially the same plane.

49. The method of claim 42 wherein said extension tubes have a pair of luer fittings fastened to the proximal ends thereof, and a closure cap on each of said luer fittings.

50. The method of claim 42 wherein said connector includes a pair of ferrules on said opposite end thereof, and said extension tubes are fastened to said ferrules.

51. The method of claim 42 wherein said extension tubes have flow control means installed on the proximal sides of said bends in said tubes.

52. The method of claim 42 wherein said Y-shaped connector forms a pair of internal passageways communicating with the dual lumens of said catheter at said one end of the connector and with said extension tubes at said opposite end of the connector.

53. The method of claim 42 wherein the bends in said extension tubes are generally U-shaped.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,895,503

DATED : January 23, 1990

INVENTOR(S) : Sakharam D. Mahurkar

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On Sheet 1, line 1, following "Sheet 1 of", "4" has been replaced with --5--.

On Sheet 2, line 1, following "Sheet 2 of", "4" has been replaced with --5--.

On Sheet 3, line 1, following "Sheet 3 of", "4" has been replaced with --5--.

On Sheet 4, line 1, following "Sheet 4 of", "4" has been replaced with --5--.

Add Drawing Sheet 5 of 5, consisting of Figs. 17 and 18, as shown on the attached page.

Signed and Sealed this

Third Day of November, 1992

Attest:

DOUGLAS B. COMER

Attesting Officer

Acting Commissioner of Patents and Trademarks

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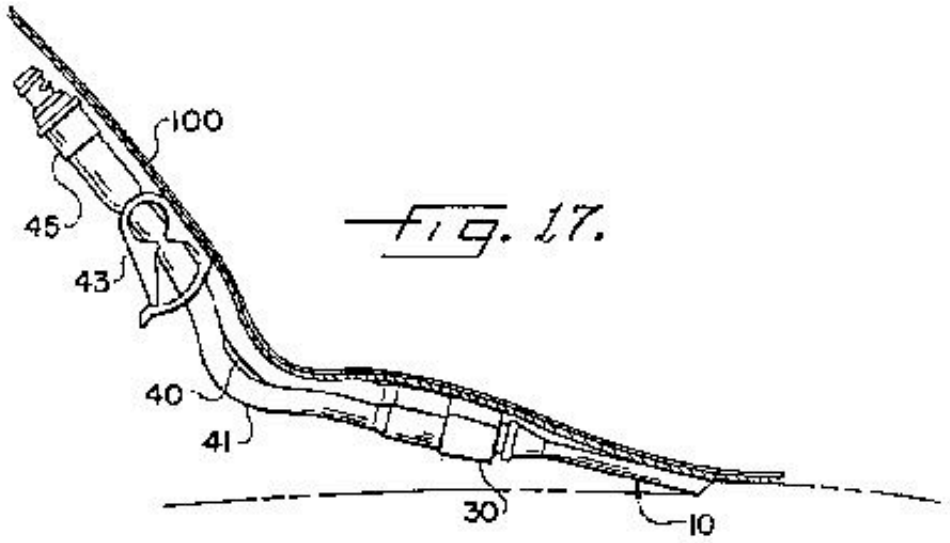

Fig. 17.

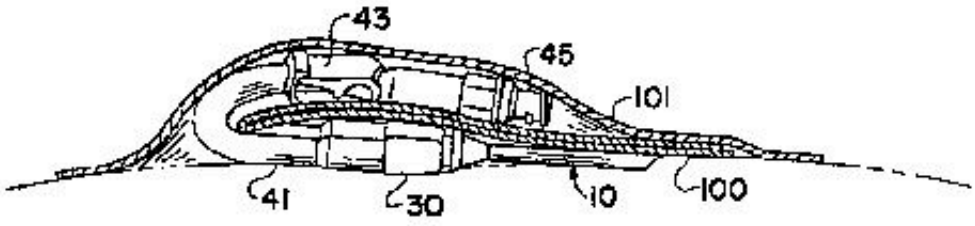

Fig. 18.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,895,561

DATED : January 23, 1990

INVENTOR(S) : Sakharam D. Mahurkar

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 6, line 6, "a direction opposite that of" should read -- the same direction as --.

Column 8, line 31, "a direction opposite that of" should read -- the same direction as --.

Column 11, line 22, "a direction opposite that of " should read -- the same direction as --.

Signed and Sealed this

Eighth Day of June, 1993

Attest:

MICHAEL K. KIRK

Attesting Officer

Acting Commissioner of Patents and Trademarks

*972

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,895,561

DATED : January 23, 1990

INVENTOR(S) : Sakharam D. Mahurkar

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 6, line 6, "a direction opposite that of" should read -- the same direction as --.

Column 8, line 31, "a direction opposite that of" should read -- the same direction as --.

Column 11, line 22, "a direction opposite that of" should read — the same direction as —.

Column 11, line 51, "a direction opposite that of" should read — the same direction as —.

Column 12, line 26, "a direction opposite that of" should read — the same direction as —.

This certificate supersedes Certificate of Correction issued June 8, 1993.

Signed and Sealed this

Twenty-seventh Day of December, 1994

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks