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(54) **MICRODIALYSIS CATHETER AND A METHOD OF MAKING A MICRODIALYSIS CATHETER**

MIKRODIALYSE-KATHETER UND VERFAHREN ZUR HERSTELLUNG EINES MIKRODIALYSE-KATHETERS

CATHÉTERS DE MICRODIALYSE ET PROCÉDÉ DE FABRICATION D'UN CATHÉTER DE MICRODIALYSE

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(73) Proprietor: **CMA/MICRODIALYSIS AB**
171 18 Solna (SE)

(72) Inventors:
- **FALKÉN, Henrik**
181 43 Lidingö (SE)
- **LISKA, Jan**
114 43 Stockholm (SE)

(74) Representative: **Holmberg, Martin Tor et al**
Bergenstrahle & Lindvall AB
P.O. Box 17704
118 93 Stockholm (SE)

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EP 2 077 762 B1

Description

FIELD OF THE INVENTION

[0001] The present invention generally relates to a microdialysis catheter for insertion into a blood vessel and a method for making the same.

BACKGROUND OF THE INVENTION

[0002] Microdialysis is used to monitor the interstitial fluid in various body organs with respect to local metabolic changes. It may also be used in blood vessels. Such a microdialysis catheter is known from e.g. US 6,346,090 Liska et al. and US 6,811,542 and US.6,264,627 also in the name of Liska et al.

[0003] US 6,811,542 uses a third transport channel in order to speed up the transport of the dialysate (the perfusate as it has passed through the dialysis chamber), which is a problem the present invention seeks to solve. The perfusate from the third channel complicates the tests made on the dialysate as well as the pumping techniques.

[0004] The invention also seeks to build a catheter which compared to the one in US 6,346,090 is easier to build.

[0005] The preamble of claim 1 is disclosed in document US 07835332.

SUMMARY OF THE INVENTION

[0006] It is an object of the invention to provide a catheter intended for insertion in e.g. a blood vessel for performing blood analyses through microdialysis. The catheter must understandably have small dimensions and the membrane must be supported in a manner such as to provide a stable and safe device. The catheter must show flexibility such as to form itself to the inside of a blood vessel and also to endure the passage through a vessel to the predetermined point where the analysis is to take place.

[0007] The present invention is disclosed by claim 1.

[0008] A further object of the invention is to be able to guide the catheter during the passage. According to the invention this is accomplished by providing a further channel in the multilumen tube, said further channel extending between the proximal end of the tube to the distal end of the tube, said further channel adapted to house guide means.

[0009] Still a further object of the invention is to give the possibility of measuring other parameters, such as blood pressure using the catheter.

[0010] According to the invention this is accomplished by providing a further channel in the multilumen tube, said further channel extending between the proximal end of the tube to the distal end of the tube, said further channel adapted to house pressure measurement means and/or sampling/delivering means.

[0011] Further objects of the invention are attained in that the tube comprises extruded biocompatible polymeric material.

[0012] Still a further object of the invention is attained by the tubular membrane being so arranged such as to have the selective layer on the outer circumference of the same.

[0013] Still a further object of the invention is attained by the membrane having a wall thickness of approx. 20-100 μm, preferably 30 to 80 μm.

[0014] Still a further object of the invention is attained by the inner diameter of the tubular membrane being approx. 1000-3000 μm, preferably 1000 -2000 μm.

[0015] A still further object of the invention is to be able to position the catheter, and to accurately determine the position of the catheter, which object according to the invention can be attained by providing means for detection of the position of the catheter in the catheter, said means responsive to ultra sound while using the same for microdialysis purposes, or by providing means for detection of the position of the catheter in the catheter, said means imparting opaqueness to X-rays to the catheter such that it is detectable using X-rays while using the catheter for microdialysis purposes.

[0016] The invention also pertains to a method of making such a catheter device as claimed in claims 1-9.

[0017] Microdialysis performed in a blood vessel requires special measures, especially when long guidable catheters are used. In order to be useful the catheter needs to provide microdialysis samples with high accuracy and with small delay times.

[0018] Another reason is that the environment, blood, poses special problems in making sure that the microdialysis actually can take place and the membrane used functions during the use of the catheter. There is always the danger of the membrane being clogged by blood components. The insertion into blood vessels requires that the catheter is flexible and that the frail membrane is supported such that it can withstand the forces applied to the catheter during insertion and also any strain applied within the blood vessel emanating from muscle etc situated around the blood vessel.

[0019] It is also extremely important the catheter does not break during use, and thereby leaving traces of the catheter in the vessel.

[0020] The invention also relates to a method of making a microdialysis catheter wherein the method comprises extniding a multilumen tube said tube exhibiting at least two longitudinally arranged inner channels, said channels extending from a proximal end of the tube to the distal end of the tube,

providing in said at least two channels through-holes one from each of said at least two channels to the outside of said tube,

blocking said channels for passage of liquid distally of the respective through-holes, arranging a tubular membrane circumferentially around the tube such as to cover the at least two through-holes, sealingly fastening said membrane to the tube thereby forming a dialysis chamber between the tube and the membrane.

[0021] The method also comprises that at least one further channel in the tube is provided during the extrusion.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] The objects and advantages and features of the present invention will be more readily understood from the following detailed description of the preferred embodiments thereof, when considered in conjunction with the drawings, in which like reference numerals indicate identical structures throughout the several views, and wherein:

Fig. 1 shows a generalised device according to the invention;
Fig. 2 shows schematically the two-channel catheter used for the invention;
Fig. 3 shows the joint between the membrane and the catheter;
Fig. 4a shows a section along the line A-A in Fig 1 in a first embodiment according to the invention;
Fig. 4b shows a section along the line B-B in Fig 1 in a first embodiment according to the invention;
Fig. 4c shows a section along the line C-C in Fig 1 in a first embodiment according to the invention;
Fig. 4d shows a corresponding section to the one in Fig. 4a in a second embodiment according to the invention;
Fig. 5 shows a corresponding section to A-A in Fig. 1 in a third embodiment where the inflow-channels and out-flow channels are doubled.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

[0023] Thus, the invention relates to a microdialysis catheter comprising a multilumen tube 10 and a membrane 11, said tube exhibiting at least two longitudinally arranged inner channels 13,14, said channels extending from a proximal end 20 of the tube to the distal end 21 of the tube, whereat through-holes 12,15 are provided, one from each of said at least two channels to the outside of said tube, said channels 13,14 blocked for passage of liquid distally of the respective through-holes, a tubular membrane 11 arranged circumferentially around the tube 10 such as to cover the at least two through-holes 12,15, said membrane is sealingly fastened 22 to the tube thereby forming a dialysis chamber 18 between the tube and the membrane.

[0024] Referring now to Figure 1, this illustrates in a side view an exemplary device according to the invention.

[0025] In Figure 1 is shown the (main tube) multilumen catheter 10 in the area where a micro-porous membrane 11 is arranged. Through the tube 10 there are two flow channels 13, 14 arranged in the longitudinal direction of the tube. Through-flow holes 12, 15 are arranged from the flow channels to the outside of the tube 10 in the section of the same covered by a micro-porous tube-formed membrane 11 arranged circumferentially of the tube. Both ends of the tube-formed membrane are glued (cf. Fig. 3) (21,22) or in any other feasible manner fastened/attached to the outside of the tube 10 forming a dialysis chamber device 18 between the membrane and the tube. The proximal end of the device is indicated at 20 and the distal end of the device is indicated at 21.

[0026] The perfusate, the liquid used in the microdialysis, enters the in-flow channel 14 and reaches the distal end of the channel where a plug 16 or the like is arranged stopping the further flow through the channel and the perfusate then exits the channel through the through-hole 15 and enters the chamber 18. The perfusate after having passed through the chamber 18 enters the return-flow channel 13 through the through-hole 12 for further passage out of the device. The channel 13 likewise exhibits a plug 17 on the distal side of the through-hole 12 forcing the perfusate/dialysate out from the catheter.

[0027] The plugs 16 and 17, as clearly can be understood from the preceding paragraph, has the sole purpose of defining the distal end of the flow channels 13, 14. It should be noted that the above describe flow pattern may be reversed.

[0028] The plugs 16, 17 are placed distally of the through-holes 15, 12. They may be placed near the through-holes, some distance away from the through-holes, 15, 12 or far away from the through-holes 15, 12, i.e. near the distal end 21 of the device. However, it is important that the plugs are placed on the distal side from the holes.

[0029] In Fig. 2 the tube in Fig. 1 is shown without the membrane in order to facilitate reading of Fig. 1. The tube 10 is shown with channels 13 and 14 with respective plug 17 and 16. In other embodiments of the invention the plug may be substituted for by any means of stopping the flow in the channel and forcing the perfusate to enter the dialysis chamber defined by the tube and the membrane.

[0030] In Fig. 3 is shown the proximal end 22 of the catheter 10 and the fastening of the membrane 11 to the tube 10. The membrane according to this embodiment of the invention is glued 22 to the tube using bio-compatible glue. Glue which is UV-curable is preferred in order to shorten production time.

[0031] In Fig. 4a the tube of Fig. 1 in a first embodiment is shown in cross-section along the line A - A indicated in Fig. 1. The membrane 11, the in-flow (14) and out-flow (13) channels of the tube 10 are shown. To illustrate the flow pattern in the dialysis chamber is shown in Fig. 4b a section along the line B-B in Fig 1 in a first embodiment according to the invention, wherein the flow is in the direction from the dialysis chamber 18 into the out-flow channel 13 and in Fig. 4c is shown a section along the line C-C in Fig 1 in the first embodiment according to the invention, wherein the flow is shown entering the dialysis chamber 18 from the in-flow channel 14.

[0032] In Fig. 4d in a second embodiment there is a further channel 19 open at both ends which may be used for insertion purposes, e.g. a guiding means could be threaded into this channel 19 for guiding the catheter to the right position. The third channel may also be used for other purposes when the guide means have been removed, e.g. for taking blood samples or for measurement of the local blood pressure.

[0033] In Fig. 5 a second embodiment is shown in which two inflow-channels 14, 24 and two out-flow channels 13, 23 are arranged the inflow through holes as well as the outflow through holes may be arranged at different heights and also the inflow and outflow channels are preferably 90°C separated or the inflow channels are separated by 180°.

[0034] The number of in-flow channel/s and out-flow channel/s may be the same or may differ. According to one embodiment, the invention relates to a microdialysis catheter comprising a multilumen tube 10 and a membrane 11, said tube exhibiting longitudinally arranged inner channels 13,14 in the form of one in-flow channel 14 and one out-flow channel 13 or two in-flow channels 14, 24 and two out-flow channels 13,23, said channels extending from a proximal end of the tube to the distal end of the tube, whereat through-holes 12,15 are provided, one from each channel to the outside of said tube, said channels 13,14 blocked for passage of liquid distally of the respective through-holes, a tubular membrane 11 arranged circumferentially around the tube 10 such as to cover the through-holes 12,15, said membrane is sealingly fastened 22 to the tube thereby forming a dialysis chamber 18 between the tube and the membrane. The features described above for the catheter also relates to this embodiment such as further channels 19 and the tube may comprise biocompatible material. Further, detection means, dimensions for a catheter and features for the membrane and the selective layer disclosed in this description also relates to this embodiment.

[0035] The total in-flow rate and the total out-flow rate according to the present invention may be 1-15 µl/minute. Further, the total in-flow rate and the total out-flow rate can be 5-15 µl/minute. By "in-flow rate" is meant the in-flow rate of the liquid going through the in-flow channel/s 14, 24, then passed to the dialysis chamber 18. In the same way, by the "out-flow rate" is meant the out-flow rate of liquid going through the out-flow channel/s 13, 23, coming from the dialysis chamber 18. This liquid is also passed through the dialysis chamber 18 and have the same flow rate through the dialysis chamber 18. Thus, the dialysis chamber flow rate is 1-15 µl/minute and the dialysis chamber flow rate may be 5-15 µl/minute. The liquid is entering the dialysis chamber 18 through the through hole 15 and exiting the dialysis chamber 18 through the through hole 12. If more than one in-flow or out-flow channel is used, there are more through holes. Thus, the dialysis chamber flow rate is the same as the total in-flow rate and the total out-flow rate.

[0036] Hence, the total in-flow rate, the total out-flow rate and the dialysis chamber flow rate have the same rate, the rate is 1-15 µl/minute. Further, the rate may be 5-15 µl/minute.

[0037] The catheter may also comprise for example one in-flow channel and two out-flow channels. When more than one out-flow channel is used, the out-flow rate in each out-flow channel can be controlled by choosing the dimension on the out-flow channels. This may be of importance for certain sensors etc.

[0038] When the same number of in-flow channels and out-flow channels are used, more than two in-flow channels and two out-flow channels (as disclosed in one embodiment above) may be used, for example three in-flow channels and three out-flow channels.

[0039] The catheters disclosed above are also made by the method according to above.

[0040] Several channels which are connected with through-holes to the outside of the tube may be used, but a practical upper limit is about six channels.

[0041] Further, the catheter may be provided with detection means for localization in order to be able to non-invasively and accurately determine the position of the catheter. This can be done using ultrasound, which requires a crystal in the catheter tip responding to ultrasound. Detection can also be achieved by the use of x-ray, requiring presence of radio opaque material in the catheter.

[0042] Exemplary dimensions for a catheter for use in a blood vessel, in a vene or in an artery, could be an outer diameter of 1 - 3mm, the inner diameter of the perfusate channels 50 - 200 µm, and the length 50 - 100 cm. For the membrane the inner diameter should be 30-200 µm larger than the outer diameter of the tube, preferably 30 - 100µm larger than the outer diameter of the tube, the wall thickness of the membrane approximately 20 - 100µm, preferably 30 - 80 µm and the length of the membrane 1 - 6 cm.

[0043] If the catheter is used in tissue the exemplary dimensions are: an outer diameter of 0.2 - 1 mm, the inner diameter of the channels 50 - 200 µm and the length 5 - 20 cm. For the membrane the inner diameter should be 30 - 200 µm larger than the outer diameter of the tube, preferably 30 - 100 µm larger than the outer diameter of the tube, the wall thickness of the membrane approximately 30 - 80 µm and the length of the membrane 0.2 - 4 cm.

[0044] For use of the catheter in blood special demands are called for in regard to the membrane. The dimension of the inner diameter is approximately 1000 - 3000 µm preferably approximately 1500 µm. The other blood-contacting surface of the membrane should be smooth reducing interactions with blood components, e.g. cells proteins. High roughness could lead to rupture of the blood cells and formation of a protein layer in the structure.

[0045] The smallest pores of the membrane should preferably be on the outside. Actually the word "pores" refer to the porous structure of a membrane, which means that they are not well-define channels rather openings in the membrane of varying width as one moves through the membrane.

[0046] The pore sizes preferably corresponding to a cut-off of approx 20,000 - 30,000 Da (measured in blood) if only glucose is to be measured. Low hydraulic permeability (Lp between $1x10^{-4}$ - $10x10^{-4}$ cm^3/cm^2 sec bar) is correlated to the cut-off.

[0047] For targeting larger molecules there will be a need for a larger cut-off, and a higher hydraulic permeability.

[0048] The selective layer should preferably be thin allowing high mass transfer rates, i.e. the selective layer should create a low overall resistance. The selective layer is a deciding factor in the microdialysis as it determines what ions and compounds that are transported through that same layer. This is important as there need to be enough substance transferred to the perfusate during the microdialysis to be analysable.

[0049] The selective layer is situated on the outer circumference of the membrane facing the blood in the blood vessel. The selective layer is preferably a few μm and then there may be e.g. four layers having different characteristics. The stability of the membrane is attained by arranging amongst those four layers one layer which is less permeable than the surrounding layers but still not as selective as the selective layer. The less permeable layer will by nature be more stable/stiff in form. This layered structure allows for sufficient mechanical stability to build the system.

[0050] The structure of the membrane should preferably be hydrophilic allowing a spontaneous wettable membrane structure. The hydrophilic character of the membrane also provides for low adsorption of proteins, giving low fouling characteristics in direct blood application. Most of the membranes used in contact with blood have a domain structure on the surface of hydrophilic and hydrophobic domains, as is known within the art, on the surface facing the blood.

[0051] As the pore sizes are small there is also a need for wettability otherwise any transfer of ions or molecules might be hampered. The perfusate liquid should make good contact with the membrane allowing for the dialysis to take place.

[0052] The surface must be highly biocompatible, i.e. low thrombogenic surface. This is a function of the domain structure on the surface. This fact is known within the art.

Claims

1. A microdialysis catheter, comprising:

    a multilumen tube (10) with two longitudinally arranged inner flow channels for perfusion fluid, extending from a proximal end (20) of the tube to a distal end (21) of the tube representing one in-flow channel (14) and one out-flow channel (13);

    through-holes (12,15), arranged from each flow channel to the outside of the tube, said flow channels (13,14) being blocked for passage of liquid by plugs (16,17) placed on the distal side of the through-holes; and

    a tubular membrane (11), arranged circumferentially around the tube (10) such as to cover the two through-holes (12,15) and sealingly fastened (22) to the tube, thereby forming a dialysis chamber (18) between the tube and the tubular membrane **characterized in that** the tubular membrane is arranged such as to have the selective layer on the outer circumference of the tubular membrane; and that the plugs (16, 17) are placed close to the through-holes (12, 15).

2. A microdialysis catheter according to claim 1, **characterized in that** there are at least one further channel (19) in the multilumen tube, said further channel extending between the proximal end of the tube to the distal end of the tube, said further channel adapted to house guide means and/or pressure measurement means and/or sampling/delivering means.

3. A microdialysis catheter according to any of the preceding claims, **characterized in that** the tube comprises extruded biocompatible polymeric material.

4. A microdialysis catheter according to any of the preceding claims, **characterized in that** the tubular membrane has a wall thickness of approx. 20 - 100 μm, preferably 30 to 80 μm.

5. A microdialysis catheter according to any of the preceding claims, **characterized in that** the inner diameter of the tubular membrane is approx. 1000 - 3000 μm, preferably 1000 -2000 μm.

6. A microdialysis catheter according to any of the preceding claims, **characterized in that** means for detection of the position of the catheter are provided in the catheter, said means responsive to ultra sound while using the same for microdialysis purposes.

7. A microdialysis catheter according to any of the preceding claims, **characterized in that** means for detection of the position of the catheter are provided in the catheter, said means imparting opaqueness to X-rays to the catheter such that it is detectable using X-rays while using the same for microdialysis purposes.

8. A microdialysis catheter according to any of the preceding claims, **characterized in that** the total in-flow

rate, the out-flow rate and the dialysis chamber flow rate have the same rate, the rate is 1-15 μl/minute.

9. A method of making a microdialysis catheter according to claim 1 to 8, **characterized by** extruding a multilumen tube,
said tube exhibiting two longitudinally arranged inner flow channels (13,14), said flow channels extending from a proximal end (20)of the tube to a distal end (21)of the tube,
providing through-holes (12,15) in said flow channels, one from each flow channel to the outside of said tube,
blocking said flow channels (13,14) for passage of liquid distally of the respective through-holes,
arranging a tubular membrane (11) circumferentially around the tube (10) such as to cover the through-holes (12,15),
sealingly fastening said membrane (22) to the tube thereby forming a dialysis chamber (18) between the tube and the membrane.

10. A method according to claim 9 in which at least one further channel in the tube is provided during the extrusion.

Patentansprüche

1. Mikrodialyse-Katheter, der Folgendes umfasst:

eine Mehrlumen-Röhre (10) mit zwei in Längsrichtung angeordneten inneren Strömungskanälen für Perfusionsfluid, die sich von einem proximalen Ende (20) der Röhre bis zu einem distalen Ende (21) der Röhre erstrecken, wobei sie einen Einströmungskanal (14) und einen Ausströmungskanal (13) darstellen,
Durchgangslöcher (12, 15), die von jedem Strömungskanal zum Äußeren der Röhre angeordnet sind, wobei die Strömungskanäle (13, 14) durch Stopfen (16, 17), die auf der distalen Seite der Durchgangslöcher angeordnet sind, für den Durchgang von Flüssigkeit gesperrt werden,
eine röhrenförmige Membran (11), die umlaufend um die Röhre (10) angeordnet ist derart, dass sie die zwei Durchgangslöcher (12, 15) abdeckt, und abdichtend an der Röhre befestigt (22) ist, wodurch sie eine Dialysekammer (18) zwischen der Röhre und der röhrenförmigen Membran bildet, **dadurch gekennzeichnet, dass** die röhrenförmige Membran derart angeordnet ist, dass sie die selektive Lage auf dem äußeren Umfang der röhrenförmigen Membran hat und dass die Stopfen (16, 17) nahe an den Durchgangslöchern (12, 15) angeordnet sind.

2. Mikrodialyse-Katheter nach Anspruch 1, **dadurch gekennzeichnet, dass** es wenigstens einen weiteren Kanal (19) in der Mehrlumen-Röhre gibt, wobei sich der weitere Kanal zwischen dem proximalen Ende der Röhre und dem distalen Ende der Röhre erstreckt, wobei der weitere Kanal dafür eingerichtet ist, Führungsmittel und/oder Druckmessungsmittel und/oder Probennahme-/Abgabemittel aufzunehmen.

3. Mikrodialyse-Katheter nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** die Röhre extrudiertes biologisch verträgliches Polymermaterial umfasst.

4. Mikrodialyse-Katheter nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** die röhrenförmige Membran eine Wanddicke von ungefähr 20 bis 100 μm, vorzugsweise 30 bis 80 μm, hat.

5. Mikrodialyse-Katheter nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** der Innendurchmesser der röhrenförmigen Membran ungefähr 1000 bis 3000 μm, vorzugsweise 1000 bis 2000 μm, beträgt.

6. Mikrodialyse-Katheter nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** Mittel zur Erfassung der Position des Katheters in dem Katheter bereitgestellt werden, wobei die Mittel auf Ultraschall ansprechen, während derselbe zu Mikrodialysezwecken verwendet wird.

7. Mikrodialyse-Katheter nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** Mittel zur Erfassung der Position des Katheters in dem Katheter bereitgestellt werden, wobei die Mittel dem Katheter Undurchlässigkeit für Röntgenstrahlen verleihen derart, dass er unter Verwendung von Röntgenstrahlen erkennbar ist, während derselbe zu Mikrodialysezwecken verwendet wird.

8. Mikrodialyse-Katheter nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** die Gesamteinströmungsrate, die Ausströmungsrate und die Dialysekammer-Strömungsrate die gleiche Rate haben, wobei die Rate 1 bis 15 μl/Minute beträgt.

9. Verfahren zur Herstellung eines Mikrodialyse-Katheters nach Anspruch 1 bis 8, **gekennzeichnet durch** das Extrudieren einer Mehrlumen-Röhre,
wobei die Röhre zwei in Längsrichtung angeordnete innere Strömungskanäle (13, 14) ausweist, wobei sich die Strömungskanäle von einem proximalen Ende (20) der Röhre bis zu einem distalen Ende (21) der Röhre erstrecken,
das Bereitstellen von Durchgangslöchern (12, 15) in

den Strömungskanälen, eines von jedem Strömungskanal zum Äußeren der Röhre,
das Sperren der Strömungskanäle (13, 14) für den Durchgang von Flüssigkeit distal von den jeweiligen Durchgangslöchern,
das Anordnen einer röhrenförmigen Membran (11) umlaufend um die Röhre (10) derart, dass sie die Durchgangslöcher (12, 15) abdeckt,
das abdichtende Befestigen der Membran an der Röhre (22), wodurch sie eine Dialysekammer (18) zwischen der Röhre und der Membran bildet.

10. Verfahren nach Anspruch 9, wobei während der Extrusion wenigstens ein weiterer Kanal in der Röhre bereitgestellt wird.

Revendications

1. Cathéter de microdialyse, comprenant :

un tube multi-lumières (10) avec deux canaux d'écoulement internes agencés longitudinalement pour un fluide de perfusion, s'étendant d'une extrémité proximale (20) du tube à une extrémité distale (21) du tube représentant un canal d'écoulement entrant (14) et un canal d'écoulement sortant (13) ;
des trous traversants (12, 15), agencés à partir de chaque canal d'écoulement vers l'extérieur du tube, lesdits canaux d'écoulement (13, 14) étant bloqués au passage de liquide par des obturateurs (16, 17) placés sur le côté distal des trous traversants ; et
une membrane tubulaire (11), agencée circonférentiellement autour du tube (10) de façon à couvrir les deux trous traversants (12, 15) et fixée de façon étanche (22) au tube, formant ainsi une chambre de dialyse (18) entre le tube et la membrane tubulaire, **caractérisé en ce que** la membrane tubulaire est agencée de façon à avoir la couche sélective sur la circonférence externe de la membrane tubulaire ; et **en ce que** les obturateurs (16, 17) sont placés à proximité des trous traversants (12, 15).

2. Cathéter de microdialyse selon la revendication 1, **caractérisé en ce qu'**il existe au moins un canal supplémentaire (19) dans le tube multi-lumières, ledit canal supplémentaire s'étendant entre l'extrémité proximale du tube et l'extrémité distale du tube, ledit canal supplémentaire étant adapté pour loger des moyens de guidage et/ou des moyens de mesure de pression et/ou des moyens de prélèvement d'échantillon/d'administration.

3. Cathéter de microdialyse selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le tube comprend un matériau polymère biocompatible extrudé.

4. Cathéter de microdialyse selon l'une quelconque des revendications précédentes, **caractérisé en ce que** la membrane tubulaire a une épaisseur de paroi d'approximativement 20 à 100 μm, de préférence 30 à 80 μm.

5. Cathéter de microdialyse selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le diamètre interne de la membrane tubulaire est d'approximativement 1000 à 3000 μm, de préférence 1000 à 2000 μm.

6. Cathéter de microdialyse selon l'une quelconque des revendications précédentes, **caractérisé en ce que** des moyens de détection de la position du cathéter sont prévus dans le cathéter, lesdits moyens réagissant aux ultrasons tout en utilisant ledit cathéter à des fins de microdialyse.

7. Cathéter de microdialyse selon l'une quelconque des revendications précédentes, **caractérisé en ce que** des moyens de détection de la position du cathéter sont prévus dans le cathéter, lesdits moyens conférant une opacité aux rayons X au cathéter de sorte qu'il puisse être détecté aux rayons X tout en utilisant ledit cathéter à des fins de microdialyse.

8. Cathéter de microdialyse selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le débit entrant total, le débit sortant et le débit de chambre de dialyse sont les mêmes, le débit étant de 1 à 15 μL/minute.

9. Procédé de fabrication d'un cathéter de microdialyse selon les revendications 1 à 8, **caractérisé par** l'extrusion d'un tube multi-lumières,
ledit tube présentant deux canaux d'écoulement internes (13, 14) agencés longitudinalement, lesdits canaux d'écoulement s'étendant d'une extrémité proximale (20) du tube à une extrémité distale (21) du tube,
la provision de trous traversants (12, 15) dans lesdits canaux d'écoulement, un à partir de chaque canal d'écoulement vers l'extérieur dudit tube,
le blocage desdits canaux d'écoulement (13, 14) au passage de liquide distalement par rapport aux trous traversants respectifs,
l'agencement d'une membrane tubulaire (11) circonférentiellement autour du tube (10) de façon à couvrir les trous traversants (12, 15),
la fixation étanche de ladite membrane (22) au tube pour ainsi former une chambre de dialyse (18) entre le tube et la membrane.

10. Procédé selon la revendication 9, dans lequel au moins un canal supplémentaire dans le tube est prévu pendant l'extrusion.

Fig. 1

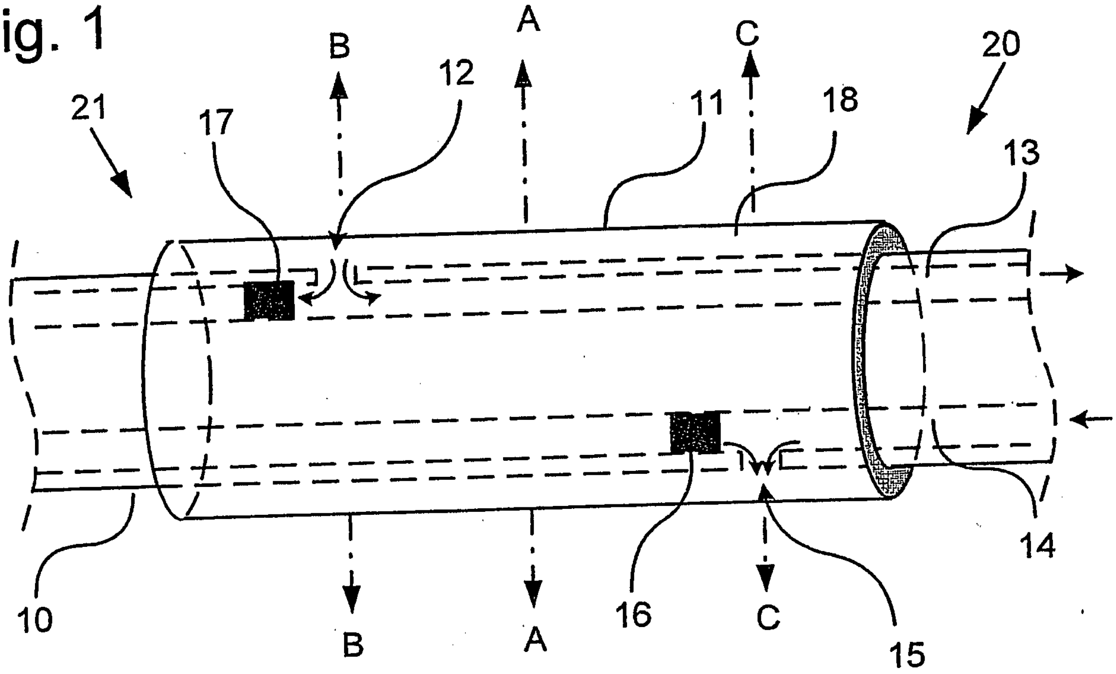


Fig. 2

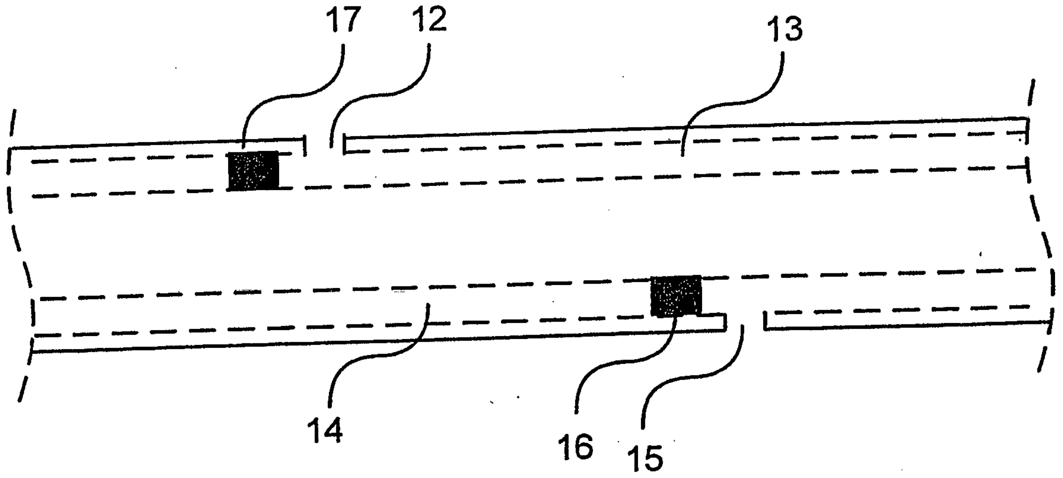


Fig. 3

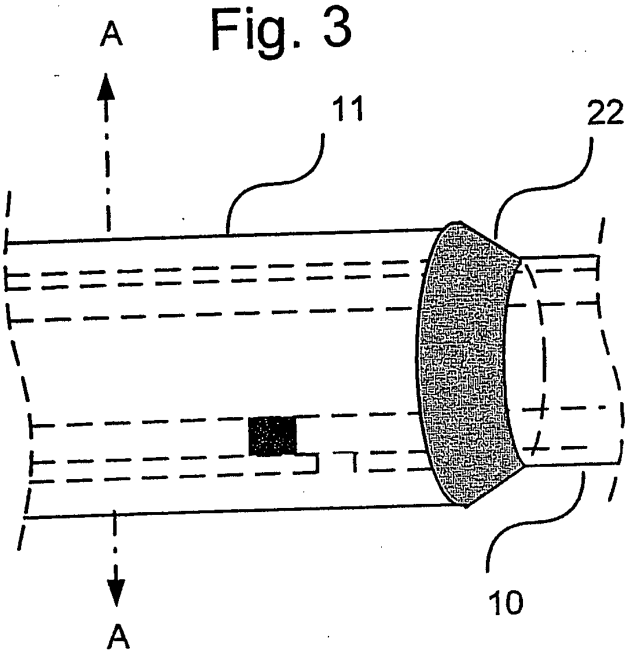


Fig. 5

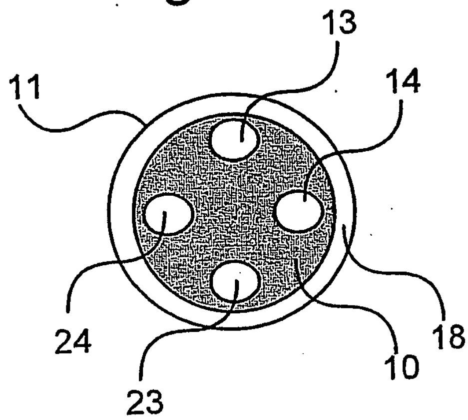


Fig. 4a

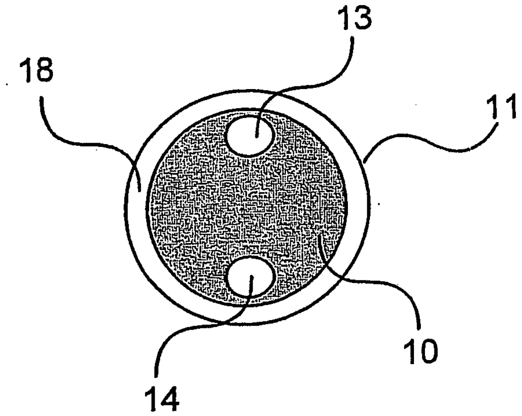


Fig. 4b

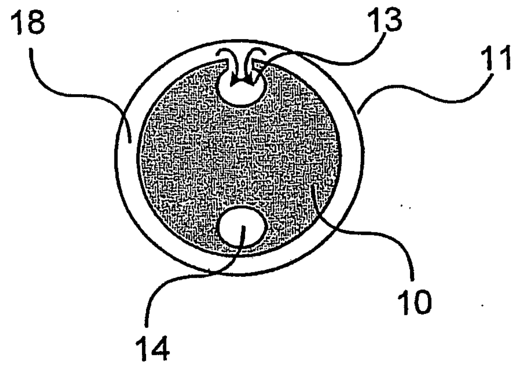


Fig. 4c

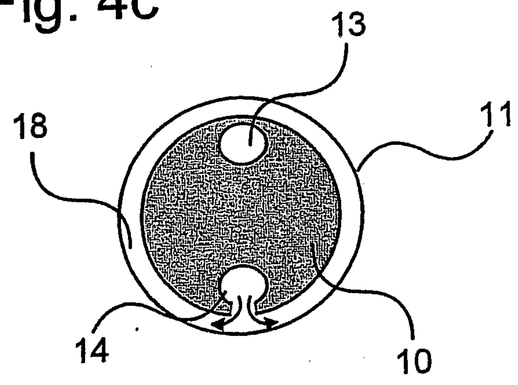
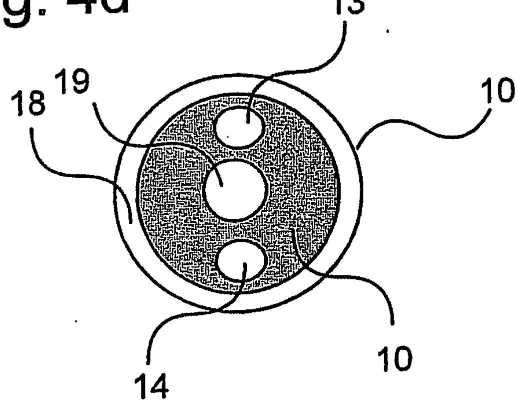


Fig. 4d



REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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- US 6811542 B **[0002] [0003]**
- US 6264627 B, Liska **[0002]**
- US 07835332 B **[0005]**

专利名称(译)	微透析导管和制造微透析导管的方法		
公开(公告)号	EP2077762A4	公开(公告)日	2010-03-17
申请号	EP2007835332	申请日	2007-10-17
申请(专利权)人(译)	CMA微透析AB /		
当前申请(专利权)人(译)	CMA微透析AB /		
[标]发明人	FALKEN HENRIK LISKA JAN		
发明人	FALKÉN, HENRIK LISKA, JAN		
IPC分类号	A61B10/00 A61M1/16 A61B5/00 A61M25/00 B29C48/32		
CPC分类号	A61B5/0215 A61B5/14528 A61B10/0045 A61M25/0009		
优先权	0602199 2006-10-18 SE 60/829883 2006-10-18 US		
其他公开文献	EP2077762A1 EP2077762B1 EP2077762B8		
外部链接	Espacenet		

摘要(译)

本发明涉及一种微透析导管，其包括多腔管（10）和膜（11），所述管具有至少两个纵向布置的内部通道（13，14），所述通道从所述管的近端（20）端延伸。 到通向管的远端（21）的地方，在通孔（12，15）上设有一个，从所述至少两个通道中的每一个到所述管的外部，所述通道（13，14）被阻塞以供通孔通过。 在各个通孔的远侧的液体中，管状膜（11）围绕管（10）沿周向布置，以覆盖至少两个通孔（12，15），所述膜密封地固定（22）至管。 从而在管和膜之间形成透析室（18）。