SLEEVE CATHETER

The invention relates to a sleeve catheter for the wetting and infiltration of a vessel wall with a fluid particularly, medicine, preferably during routine treatment with a balloon catheter.

For the treatment of constricted passages in arteries, balloon dilation is recognized as an only little invasive but very effective and elegant method. Experience however shows that this treatment method has a high recurrence rate in the order of about 30% of the treated patients, that is, within a period of several months, for example, between 3 and 6 months, passage constriction will reoccur. It has been shown that this is at least partly caused by cell growth which is caused by the balloon dilation, that is, by expansion and rupture of the tissue. It is therefore desirable to provide for the vessel area which is subjected to such balloon dilation additional treatment which counteracts such tissue growth.

Various methods for growth-inhibiting treatment are known, particularly, the application of energy, for example, by means of a laser or the localized treatment with special medicine. As carrier for the localized treatment with medicine it is known to use wire wall supports (so-called stents) whose use however is complicated and which cannot be removed.

This Sheet Has Been Replaced



It has also been proposed to use balloon catheters with perforated balloons so that, during the dilation procedure, medication can be administered for penetration into the tissue. However, this proposal was found to be unsuitable since already at the beginning of, and during, balloon expansion, uncontrollable amounts of medicine are lost so that it becomes impossible to apply a defined amount of medicine to the tissue wall areas to be treated for wetting of the tissue and infiltration into the tissue wall. During inflation of the balloon, that is, before the balloon wall abuts the vessel wall, a substantial amount of the medicine is released and this prematurely released amount of medicine does not reach the vessel layers to be treated and, consequently, an undesirably high dosage is required if the particular vessel area to be treated is to be exposed to a sufficient amount of medicine. Another disadvantage is seen in the fact that only an insufficient amount of pressure can be generated with a perforated balloon which may not be enough to expand the restricted vessel area.

It is desirable to overcome the disadvantages as described in connection with a perforated balloon, wherein however the effectiveness and the elegance of balloon dilation should be maintained and medication treatment of the tissue and the vessel wall should be facilitated during the same procedure without essential additional time input. It is therefore the object of the invention to improve the established balloon catheter procedure such that, on one hand, the high recurrence rate can be reduced by the simultaneous administration of medicine, and, on the other hand, the medicine is administered in the desired dosage and is applied essentially only to the tissue areas to be treated.

In a sleeve catheter for supplying medicine to the walls of a vessel or tubular organ in which a number of outer lumina extend longitudinally around a central

This Sheet Has Been Replaced



lumen, the outer lumina have radial discharge openings in the area of the head portion of the catheter, which is slidable onto a balloon catheter in order to be disposed at least partially on the balloon of the balloon catheter so as to be expandable thereby into abutment with the inner wall of a vessel to be dilated whereby medicine can be supplied through the discharge openings in the outer lumina under pressure directly to the tissue of the vessel adjacent the outer lumina, thereby applying the medicine solely to the area engaged by the outer surface of the head portion.

The arrangement according to the invention has the advantage that the sleeve catheter is slidable onto a portion of the deflated balloon of a balloon catheter, so that the low balloon profile as required for the insertion of the catheter into constricted vessel area is essentially maintained. Inflation of the balloon forces the head portion of the sleeve catheter into engagement with the tissue to be treated so that, during the dilation procedure the medicine can be applied, under pressure, through the outer lumina directly to the tissue to be treated whereby it enters solely this tissue. In this manner all toxic compounds or gene-technologically designated medicine adapted to inhibit undesirable cell growth in the treated area can be injected directly and only into the tissue area to be treated.

In a further embodiment according to the invention the perforations are preformed such that they are opened by application of the balloon pressure. They may also be preformed in such a manner that they are opened by the application of additional pressure to the outer lumina.

In order to facilitate the expansion of the head portion of the sleeve catheter, in another embodiment, the head portion is provided at its outside between the discharge openings with longitudinally extending radial notches. Expansion can be further facilitated by

This Sheet Has Been Replaced



providing longitudinally extending radial notches also in the inner wall, between the outer lumina, which is disposed adjacent the inner lumen of the catheter.

In order to administer the medicine as locally as possible, that is, only in the close proximity of the constricted vessel area, or stenosis, it is advantageous if the discharge openings are preformed in such a manner that they are opened gradually with increasing pressure, beginning at the distal end, toward the proximal end of the head portion. Depending on the location where the sleeve catheter is to be used in connection with a balloon catheter, in vessels or in organs, it may be advantageous to administer different amounts of medicine for wetting the tissue or infiltration into the tissue. It is therefore within the scope of the present invention to provide distributed over the circumference of the head portion, six to twenty outer lumina.

The advantages and features of the invention are apparent from the following description of an embodiment described below with reference to the drawings and defined in the claims.

Figure 1 shows the head portion of a sleeve catheter disposed on a balloon catheter;

Fig. 2 is a cross-sectional view of the front end of the balloon catheter with the head portion of the sleeve catheter disposed thereon;

Fig. 3 is a cross-sectional view of the inflated balloon with an expanded head portion of the sleeve catheter,

Fig. 4 is a cross-sectional view along lines IV-IV of Fig. 1; and

Fig. 5 shows the connecting structure for the operation of the balloon catheter and the sleeve catheter.

This Sheet Has Been Replaced



Figs. 1, 2 and 3 show the details of a sleeve catheter 10 disposed on a balloon catheter 11. The sleeve catheter is slipped onto the balloon catheter such that the head portion 16 extends at least partially over the balloon 12 which is mounted on a flexible guide rod 14 as shown in Fig. 2. In these relative positions the two catheters are inserted into a vessel or an organ. The outer lumina 18 terminate in the head portion of the sleeve catheter and they extend over the full length of the sleeve catheter up to the connecting structure which is shown in Fig. 5 and explained below. As shown the outer lumina 18 are arranged in a circle around a central lumen 20 wherein 6 to 20 outer lumina may be provided depending on the size and the application area of the sleeve catheter.

It is also possible to provide only one or two lumina which extend along the sleeve catheter and which are divided in the head portion into several outer lumina. The cross-section and the arrangement of the lumina are adapted to a particular application.

In the cross-sectional view of Fig. 4 which is taken across a head portion 16 disposed on a balloon catheter 11, there are eight outer lumina 18 which are provided with discharge openings 24 leading to the outside of the head portion. These discharge openings 24 are so designed that they open only toward the end of balloon pressure application and then discharge a medicine contained in the outer lumina 18. It is also possible to preform the discharge openings in such a way that they open only by application of additional pressure applied via the connecting structure.

In order to facilitate expansion of the head portion 16 it is provided, at least on the outside, with radial grooves 22 which extend longitudinally between the discharge openings 24 and to a limited depth spaced from the inner wall of the head portion so as to provide for a

This Sheet Has Been Replaced



hinge structure allowing the radial grooves 22 to open up and expand the head portion with only small pressure requirements. In order to further reduce the pressure required for the expansion of the head portion further radial grooves 23 may be provided at the inside of the head portion adjacent the central lumen 20, the grooves 23 extending longitudinally between the outer lumina 18. If two radial grooves 23 are provided at opposite sides of a radial groove 22, three-hinge structures are formed which further facilitate expansion of the head portion.

With this arrangement the head portion can be pressed in sufficiently tight contact with the vessel walls by the pressure of, for example, 5 to 8 bar required for full expansion of the balloon so that the medicine, when applied through the outer lumina 18 and the discharge openings 24, will not flow away but will be applied to the inner wall surface in a highly localized fashion such that it will penetrate the wall and then infiltrate the inner layers in sufficiently high concentrations.

For good distribution of the medicine during dilation when the head portion is firmly pressed against the expanded tissue by the pressure built up in the inner balloon, that is, in order to inject the medicine essentially in the center area of the constriction being treated, the discharge openings 24 are preferably preformed in such a manner that they open with increasing pressure beginning at the distal end of the head portion toward the proximal end. With this arrangement it is insured that the injected medicine is not carried away but is applied in sufficiently high concentration to the tissue layers as desired and subsequently infiltrates into the deeper wall layers. The amount of medicine released into the vessel after deflation of the catheter which normally takes place after about 60 seconds is then relatively small and it is diluted in a material way so that as far as the dose is concerned it is irrelevant for

This Sheet Has Been Replaced



the total body system even if a large dose was applied localized to the treated vessel area. For application, primarily already well known cell-toxic compounds are used whose effects can be well determined but also genetically designed medicine may be used.

Utilization of pressure generators (indeflator) as normally used in connection with balloon dilation permits injection and infiltration of medicine into the tissue under any desired pressure and in any desired predetermined amount.

Fig. 5 shows a connecting structure for an indeflator and for an operating mechanism for injecting a medicine. The connecting structure comprises a Y connector with a terminal 32 for scavenging and a terminal 34 for the indeflator. The balloon catheter 11 is connected to this Y connector. The sleeve catheter 10 which surrounds the balloon catheter 11 is provided at its rear end with a connecting structure 36 which has a terminal 37 through which the medicine is supplied by means of a pressurizer which is not shown in the drawing. Within the connecting structure 36 the terminal 37 is connected to the outer lumina 18 of the sleeve catheter.

With this connecting structure arrangement the balloon dilation can be performed independently of the application of the medicine so that the medicine can be administered independently and in predetermined amounts.

For the treatment of coronary vessels the invention provides for a substantial advantage in that the elegance of the balloon dilation method is maintained and the procedure is not extended because the medicine is injected during the normal dilation procedure during which, furthermore, an exactly defined amount of medicine is administered within a well determined vessel area.

However the arrangement according to the invention is suitable not only for treatment of coronary vessels but also for kidney vessels and vessels in extremities and, depending on the conditions, also for vessels

This Sheet Has Been Replaced



in the head of a patient. It may also be used for the wetting and infiltration of growth-inhibiting compounds in vessel portions of organs or tubular systems such as the urethra or the bile duct or other vessel-like organs. The arrangement according to the invention is also particularly well suited for the treatment of cancerous areas with growth-inhibiting compounds (in this case cytostatics). The arrangement further permits treatment of tubular structures riddled with carcinoma without endangering or blocking passage therethrough that is also malicious sicknesses in the area of the trachea or the intestines can be treated in accordance with the invention without disturbing passage through the affected areas. Also for the treatment of prostate hypertrophy medicine can be administered in the described manner.

This Sheet Has Been Replaced



What is claimed is:

1. A sleeve catheter for the wetting and infiltration of a vessel wall or other tubular organ by a fluid, particularly a liquid medicine,
characterized in that

said sleeve catheter (10) comprises a head portion (16) with a central lumen (20) and a number of outer lumina (18) extending in cross section in a circle around said central lumen, each having discharge openings (24) formed in the head portion (16) thereof,

said sleeve catheter (10) is adapted to be slidable with its central lumen (20) onto a balloon catheter (11), so as to be disposed at least partially on the balloon of said balloon catheter,

said portion (16) of said sleeve catheter is expandable for engaging the inner wall of a vessel to be expanded upon inflation of said balloon (12), and

said fluid is supplied to said outer lumina (18) under pressure so as to be applied to said vessel wall via said discharge openings (24) when said head portion is in engagement with the inner wall of the vessel wall to be treated.

2. A sleeve catheter according to claim 1,
characterized in that

said discharge openings (24) are perforated such that they open by the application of the balloon pressure.

* C L M S *

This Sheet Has Been Replaced

3. A sleeve catheter according to claim 1,
characterized in that
said discharge openings (24) are preformed such that they are opened by the application of an additional pressure to the outer lumina (18).

4. A sleeve catheter according to any one of claims 1 to 3,
characteriozed in that
said head portion (16) includes, at its outside, longitudinally extending radial grooves (22) arranged between said discharge openings.

5. A sleeve catheter according to claim 4,
characterized in that
longitudinally extending radial grooves (23) are provided between said outer lumina (18) also in the inner wall of said lead portion adjacentto the central lumen (20).

6. A sleeve catheter according to one or more of claims 1 to 5,
characterized in that
said discharge openings (24) are preformed in such a way that they are opened successively with increasing pressure beginning at the distal end of the head portion and continuing toward the proximal end of the head portion (16).

7. A sleeve catheter according to one or more of claims 1 to 6,
characterized in that
said head portion (16) includes six to twenty outer lumina (18) distributed over its circumference.

* C L M S *

This Sheet Has Been Replaced

SLEEVE CATHETER

Abstract of the Disclosure

In a sleeve catheter (10) for supplying medicine to the walls of a vessel or tubular organ in which a number of outer lumina (18) extend longitudinally around a central lumen, the outer lumina have radial discharge openings (24). The area of the head portion (16) of the catheter which is slidable onto a balloon catheter (11) is expandable to thereby abut with the inner wall of a vessel. The fluid can be supplied through the discharge openings (24) in the outer lumina under pressure directly to the tissue of the vessel adjacent the outer lumina. Thereby medicine can be applied easily to a limited area inside the body.

(Fig. 1)

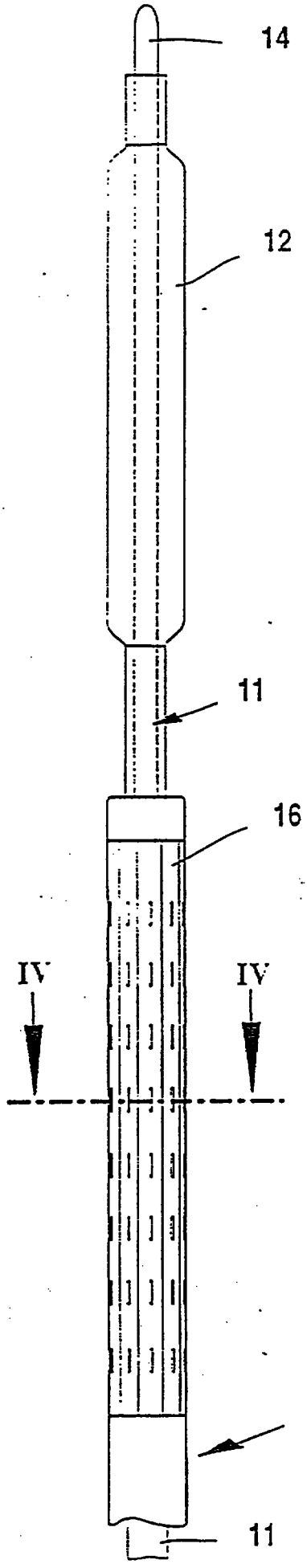


Fig. 1

This Sheet Has Been Replaced

This Sheet Has Been Replaced

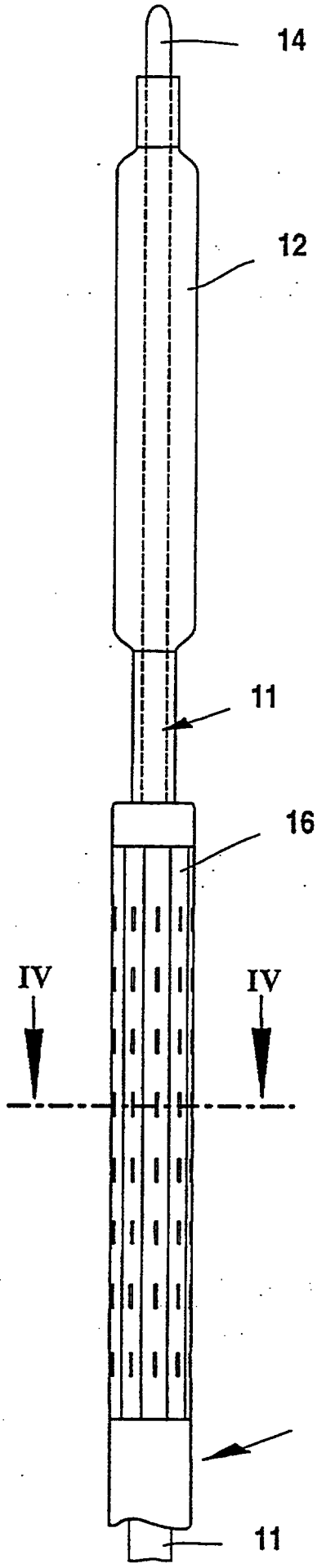


Fig. 1

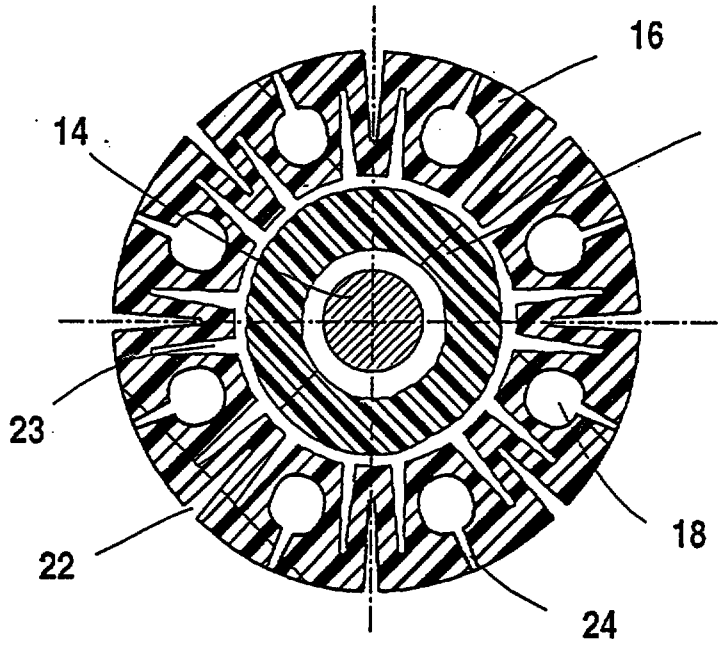


Fig. 4

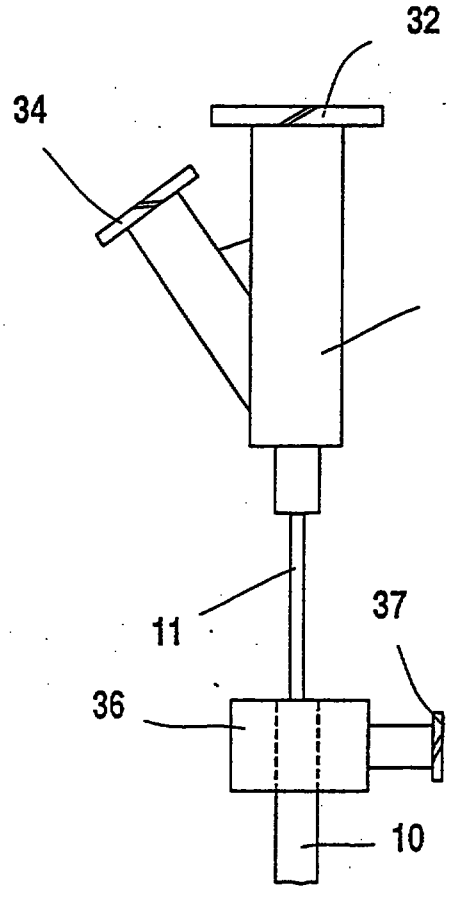


Fig. 5

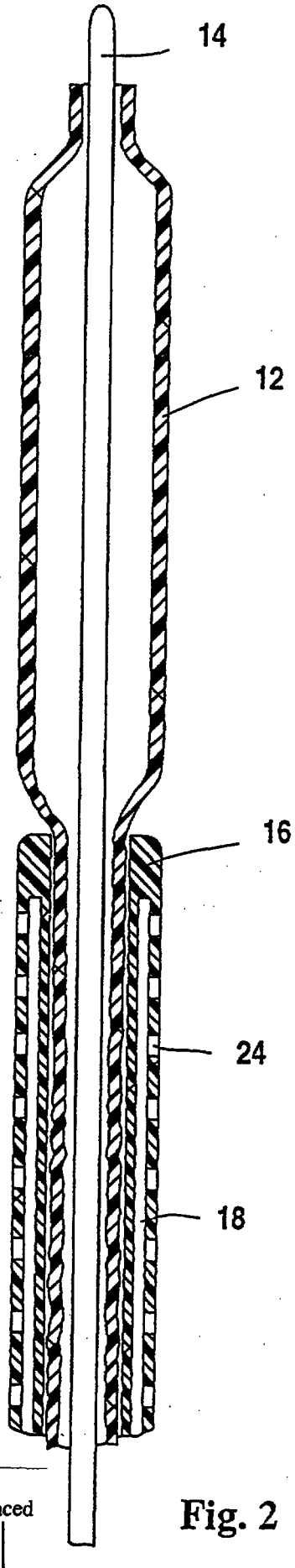


Fig. 2

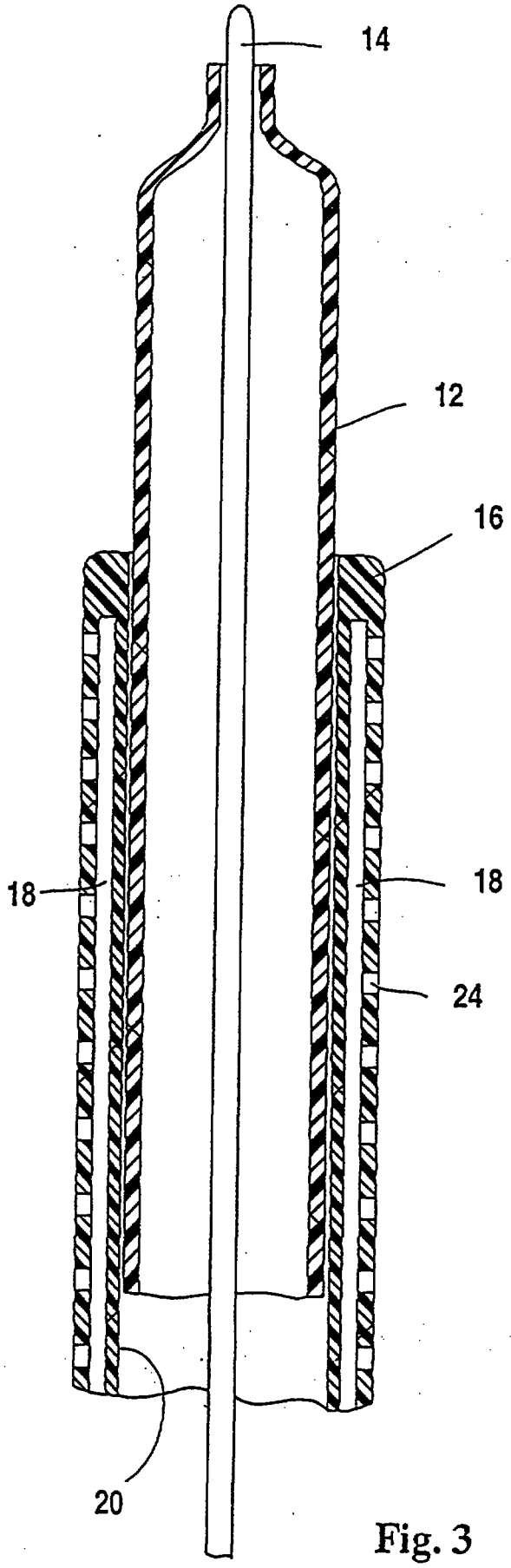


Fig. 3

This Sheet Has Been Replaced

Manschettenkatheter

Die Erfindung betrifft einen Manschettenkatheter zur Benetzung und Infiltration einer Gefäßwand mit einem Fluid, insbesondere einem Arzneimittel, vorzugsweise während der routinemäßigen Behandlung mit einem Ballonkatheter.

Für die Behandlung von Gefäßverengungen in Arterien ist die Ballondilatation als wenig invasive, sehr wirkungsvolle und elegante Methode anerkannt. Die Erfahrung lehrt jedoch, daß die Behandlungsmethode eine hohe Rezidivrate in der Größenordnung von etwa 30% der behandelten Patienten hat, d.h. die Gefäßverengung stellt sich innerhalb von mehreren Monaten, z. B. zwischen 3 und 6 Monaten wieder ein. Es gilt als nachgewiesen, daß dabei Zellwachstumsvorgänge eine Rolle spielen, die durch die Ballondilatation, d.h. die Aufweitung und das Reißen des Gewebes ausgelöst werden. Es ist daher wünschenswert, in dem der Ballondilatation unterworfenen Gefäßbereich eine Zusatzbehandlung durchzuführen, die einem solchen Gewebewachstum entgegenwirkt.

Es sind unterschiedliche Methoden für wachstumshemmende Eingriffe bekannt, insbesondere durch Energieapplikation, z.B. mit einem Laser, oder durch lokale Medikamentenverabreichung. Als Träger der lokalen Medikamentenverabreichung sind sog. Stents (Drahtwandstützen) bekannt, deren Einsatz jedoch umständlich ist, und die sich auch nicht entfernen lassen.

Es wurde auch schon vorgeschlagen Ballonkatheter zu benutzen, bei denen der Ballon perforiert ist, so daß während der Ballondilatation ein Arzneimittel appliziert werden kann, das in das Gewebe eindringen soll. Dieser Vorschlag erweist sich jedoch als unzweckmäßig, da bereits zu Beginn und während der Ballonentfaltung unkontrollierbare Mengen des Arzneimittels verloren gehen, so daß es nicht möglich ist, während der Behandlung eine definierte Arzneimittel-

menge für die Benetzung des Gewebes und das Eindringen in die Gefäßwand in dem zu behandelnden Bereich der Gefäßwand zu verabreichen. Beim Aufblasen des Ballons, und zwar bevor sich der Ballon an der Gefäßwand anlegt, fließt nämlich bereits ein wesentlicher Anteil des Medikaments mit dem Ergebnis ab, daß die vorzeitig freigesetzte Arzneimittelmenge nicht an die zu behandelnden Gefäßschichten gelangt, oder daß eine unerwünscht hohe Dosierung erforderlich ist, um den lokal zu behandelnden Gefäßbereich ausreichend mit dem Arzneimittel zu beeinflussen. Ein weiterer Nachteil wird darin gesehen, daß in einem perforierten Ballon nicht genügend Druck aufgebaut werden kann, um das verengte Gefäß aufzuweiten.

Es ist wünschenswert die in Verbindung mit einem perforierten Ballon geschilderten Nachteile zu überwinden. Dabei soll die Effektivität und die Eleganz der Ballondilatation erhalten bleiben und während des gleichen Eingriffs ohne wesentlichen zusätzlichen Zeitaufwand eine medikamentöse Behandlung des Gewebes und der Gefäßwand ermöglicht werden. Es ist daher Aufgabe der Erfindung die etablierte Ballonkathetertechnik so zu erweitern, daß einerseits die hohe Rezidivrate durch gleichzeitige Arzneimittelapplikation herabgesetzt werden kann, wobei gewährleistet ist, daß das Arzneimittel in der gewünschten Dosierung im wesentlichen nur an die zu behandelnden Gewebeteile gelangt.

Diese Aufgabe wird ausgehend von dem eingangs erwähnten Manschettenkatheter erfindungsgemäß dadurch gelöst, daß der Manschettenkatheter einen Kranz von im Querschnitt um ein zentrales Lumen verteilte Außenlumina aufweist, die im Kopfsegment in Austrittsöffnungen enden, daß der Manschettenkatheter mit seinem zentralen Lumen auf einen Ballonkatheter aufschiebbar ist, wobei der Ballon zumindest teilweise übergriffen wird, daß sich das Kopfsegment des Manschettenkatheters durch Aufblasen des Ballons bis zur Anlage an die Innenwand des Gefäßes aufweiten läßt, und daß das über die Außenlumina zugeführte bzw. in diese eingefüllte Fluid mit Hilfe eines angelegten Drucks durch die Austrittsöffnungen in das Gefäß bzw. die Gefäßwand applizierbar ist.

Die Maßnahmen der Erfindung bieten den Vorteil, daß der Manschettenkatheter auf einen Teil des deflatierten Ballons eines Ballonkatheters aufschiebbar ist, so daß das niedrige Ballonprofil, das zum Eindringen in eine Gefäßverengung

notwendig ist, nicht verschlechtert wird. Durch das Aufblasen des Ballons wird das Kopfsegment des Manschettenkatheters gegen das zu behandelnde Gewebe gedrückt, so daß im Stadium der Dilatation das gewünschte Arzneimittel zusätzlich durch die Außenlumina und die Austrittsöffungen unmittelbar in das zu behandelnde Gewebe eingepreßt werden kann und in das Gewebe eindringt. Damit können zur Unterdrückung des angeregten Zellwachstums im Behandlungsbereich sowohl zelltoxisch wirkende Substanzen als auch gentechnologisch designierte Medikamente unmittelbar in den zu behandelnden Gewebebereich injiziert werden.

Eine weitere Ausgestaltung der Erfindung sieht vor, daß die Austrittsöffnungen präformiert sind und sich durch die Applikation des Ballondrucks öffnen. Es ist auch vorgesehen, daß die Austrittsöffnungen präformiert sind und sich durch die Applikation eines zusätzlichen Drucks auf die Außenlumina öffnen.

Um die Aufweitung des Kopfsegments des Manschettenkatheters zu begünstigen, sieht eine weitere Ausgestaltung der Erfindung vor, daß das Kopfsegment auf der Außenseite zwischen den Austrittsöffnungen mit in Längsrichtung verlaufenden Radialeinschnitten versehen ist. Das Aufweiten kann weiter begünstigt werden, indem auch in der das zentrale Lumen begrenzenden Innenwand zwischen den Außenlumina in Längsrichtung verlaufende Radialschnitte vorhanden sind.

Für die möglichst lokale Verabreichung eines Medikaments im unmittelbaren Bereich der Gefäßverengung oder Stenose ist es auch zweckmäßig, daß die Präformation der Austrittsöffnungen derart ausgeführt ist, daß sich die Austrittsöffnungen mit ansteigendem Druck vom distalen Ende ausgehend zum proximalen Ende des Kopfsegmentes hin verlaufend öffnen.

Je nach dem Anwendungsort des Manschettenkatheters in Verbindung mit einem Ballonkatheter in Gefäßen oder Organen kann es wünschenswert sein, unterschiedliche Arzneimittelmengen für die Gewebebenetzung bzw. Infiltration in das Gewebe zu applizieren. Aus diesem Grund sieht die Erfindung vor, daß über den Umfang des Kopfsegmentes zwischen sechs bis zwanzig Außenlumina verteilt vorgesehen sind.

Die Vorteile und Merkmale der Erfindung ergeben sich auch aus der nachfolgenden Beschreibung eines Ausführungsbeispiels in Verbindung mit den Ansprüchen und der Zeichnung. Es zeigen:

Fig. 1 das auf einen Ballonkatheter aufgeschobene Kopfsegment eines Manschettenkatheters;

Fig. 2 einen Schnitt durch das vordere Ende des Ballonkatheters mit aufgeschobenem Kopfsegment;

Fig. 3 einen Schnitt durch einen aufgeblasenen Ballon mit einem aufgeweiteten Kopfsegment des Manschettenkatheters;

Fig. 4 einen Schnitt längs der Linen IV - IV der Fig. 1;

Fig. 5 die Anschlußvorrichtungen zum Betätigen des Ballonkatheters und des Manschettenkatheters.

Aus den Fig. 1, 2 und 3 gehen Einzelheiten des auf einen Ballonkatheter 11 aufgeschobenen Manschettenkatheters 10 hervor. Der Manschettenkatheter ist auf den Ballonkatheter aufgeschoben, wobei das Kopfsegment 16 den Ballon 12 zumindest teilweise übergreift, wie aus Fig. 2 hervorgeht. In dieser Zuordnung werden die beiden Katheter in ein Gefäß oder Organ eingeführt. Im Kopfsegment des Manschettenkatheters enden die Außenlumina 18, welche sich über die gesamte Länge des Manschettenkatheters bis zu der in Fig. 5 dargestellten und später erläuterten Anschlußvorrichtung erstrecken. Es ist vorgesehen, daß diese Außenlumina 18 in einem Kranz um ein zentrales Lumen 20 angeordnet sind, wobei je nach Größe und Anwendungsgebiet des Manschettenkatheters zwischen 6 bis 20 Außenlumina 18 vorgesehen sein können.

Eine nicht dargestellte Ausführungsform sieht auch vor, daß in Längsrichtung des Manschettenkatheters nur ein Lumen bzw. 2 Lumina verlaufen, die sich im Kopfsegment in mehrere Außenlumina aufteilen können. Der Querschnitt und die Anordnung der Lumina wird an den jeweiligen Anwendungsfall angepaßt.

In dem in Fig. 4 dargestellten Schnitt durch das auf einem Ballonkatheter 11 aufgeschobene Kopfsegment 16 sind acht Außenlumina 18 vorgesehen, die

Austrittsöffnungen 24 zur Außenseite des Kopfsegmentes haben. Für die Gestaltung dieser Austrittsöffnungen 24 ist vorgesehen, daß sie sich erst gegen Ende der Applikation des Ballondruckes öffnen und ein im Außenvolumen 18 befindliches Medikament austreten lassen. Es ist auch vorgesehen, die Austrittsöffnungen präformiert so auszugestalten, daß sie sich durch die Applikation eines zusätzlichen über die Anschlußvorrichtung zugeführten Druckes öffnen.

Um das Aufweiten des Kopfsegmentes 16 zu erleichtern, ist dieses zumindest auf der Außenseite zwischen den Austrittsöffnungen 24 mit in Längsrichtung verlaufenden Radialeinschnitten 22 versehen, die nicht durch die Innenwand des Kopfsegmentes hindurchgehen. Dadurch entsteht ein Gelenk, aufgrund dessen sich der Radialeinschnitt 20 öffnen kann und die Aufweitung des Kopfsegmentes mit einem geringeren Druckaufwand möglich ist. Um den für die Aufweitung benötigten Druck weiter zu verringern, können weitere Radialeinschnitte 23 auf der das zentrale Lumen begrenzenden Innenseite des Kopfsegmentes vorgesehen sein, die in Längsrichtung zwischen den Außenlumina 18 verlaufen. Wenn beiderseits des Radialeinschnittes 22 zwei Radialeinschnitte 23 vorgesehen sind, ergeben sich drei Filmgelenke, die das Aufweiten des Kopfsegmentes weiter erleichtern.

Bei dieser Ausgestaltung kann das Kopfsegment mit dem für die vollständige Ausdehnung des Ballons benötigten Druck von beispielsweise 5 bis 8 bar genügend fest an die Gefäßwand angedrückt werden, so daß bei der Applikation des Arzneimittels durch die Außenlumina 18 und die Austrittsöffnungen 24 dieses nicht abfließt, sondern mit genügend hoher Konzentration an die Wandinnenschicht gebracht und anschließend in tiefere Wandschichten mit genügend hoher Konzentration infiltriert werden kann.

Um die Verteilung des Arzneimittels im Stadium der Dilatation, wenn das Kopfsegment durch den im innenliegenden Ballon aufgebauten Druck gegen das gesprengte Gewebe gedrückt wird, möglichst im Zentrum der behandelten Engstelle injizieren zu können, ist vorgesehen, daß die Präformation der Austrittsöffnungen 24 derart ausgeführt ist, daß sich diese Austrittsöffnungen mit ansteigendem Druck vom distalen Ende ausgehend zum proximalen Ende des Kopfsegmentes hin verlaufend öffnen. Damit wird gewährleistet, daß das

injizierte Arzneimittel nicht abfließt, sondern in genügend hoher Konzentration in die gewünschten Gewebeschichten und die anschließenden tieferen Wandschichten eingepreßt und infiltriert wird. Die nach der Katheterdeflation, welche in der Regel nach ca. 60 sek. stattfindet, eventuell noch im Gefäß freigesetzten Arzneimittelmengen sind dann verhältnismäßig gering und werden auf natürlichem Weg erdünnt, so daß sie für das Gesamtkörpersystem dosismäßig keine Rolle spielen, selbst wenn sie für den lokalen Gefäßabschnitt in hochdosierten Mengen appliziert werden. Für die Applikation kommen in erster Linie bereits wohlbekannte und in ihrer Wirkung gut abschätzbare zelltoxische Substanzen oder auch gentechnologisch designierte Medikamente in Frage.

Durch die Verwendung der üblichen bei der Ballondilatation benutzen Druckgeneratoren (Indeflator) können die Arzneimittel unter beliebig hohem Druck und in beliebiger, vorher festgelegter Menge in das Gewebe injiziert bzw. infiltriert werden.

In Fig. 5 ist die Anschlußvorrichtung für einen Indeflator sowie für eine Betätigungseinrichtung zum Einpressen eines Arzneimittels dargestellt. Diese Anschlußvorrichtung besteht aus einem Y-Konnektor mit einem Anschluß 32 für die Spülung und einem Anschluß 34 für den Indeflator. An diesen Y-Konnektor ist der Ballonkatheter 11 angeschlossen. Der auf den Ballonkatheter 11 aufgeschobene Manschettenkatheter 10 ist am hinteren Ende mit einem Konnektor 36 versehen, der einen Anschluß 37 hat, über welchen das Arzneimittel mit Hilfe eines nicht dargestellten Druckgenerators zugeführt werden kann. Innerhalb des Konnektors 36 ist der Anschluß 37 an die Außenlumina 18 des Manschettenkatheters angeschlossen.

Durch diese Ausgestaltung der Anschlußvorrichtung kann die Ballondilatation unabhängig von der Applikation des Arzneimittels erfolgen, und, wie bereits erwähnt, das Arzneimittel in beliebiger sowie festgelegter Menge verabreicht werden.

Bezogen auf die Behandlung von Herzkranzgefäßen liegt ein wesentlicher Vorteil der Erfindung darin, daß die Eleganz der Ballondilatationsmethode erhalten bleibt und der Eingriff nicht verlängert wird, weil die Injektion während der

üblichen Ballondilatation erfolgt und eine genau definierbare Arzneimittelmenge in einem genau ersichtlichen Gefäßsegment appliziert werden kann.

Die Erfindung ist jedoch nicht nur für die Anwendung in Herzkranzgefäßen, sondern auch in Nierengefäßen, Extremitätengefäßen und gegebenenfalls auch in Kopfgefäßen geeignet. Sie kann auch für die Benetzung und Infiltration von Gefäßsegmenten mit wachstumshemmenden Substanzen in Organen oder röhrenförmigen Systemen Verwendung finden, wie z.B. der Harnröhre, der Gallengänge und anderen gefäßartigen Organen. Insbesondere für die Behandlung von krebserkrankten Bereichen mit wachstumshemmenden Substanzen (in diesem Fall Zytostatika) ist die Erfindung besonders gut geeignet. Damit wird die Behandlung von röhrenförmigen und von Karzinom befallenen Strukturen möglich, ohne den Transport durch diese Strukturen zu gefährden, d.h. auch bösartige Erkrankungen im Trachealraum oder im Darm können nach diesem Prinzip behandelt werden, ohne daß die Passage durch die erkrankte Struktur gestört wird. Auch für die Behandlung der Prostatahypertrophie können Medikamente auf die beschriebene Weise herangeführt werden.

PATENTANSPRÜCHE

1. Manschettenkatheter zur Benetzung und Infiltration einer Gefäßwand oder anderen röhrenförmigen Organen mit einem Fluid, insbesondere einem Arzneimittel,
dadurch gekennzeichnet,
- daß der Manschettenkatheter (10) einen Kranz von im Querschnitt um ein zentrales Lumen (20) verteilten Außenlumina (18) aufweist, die im Kopfsegment (16) in Austrittsöffnungen (24) enden,

- daß der Manschettenkatheter (10) mit seinem zentralen Lumen (20) auf einen Ballonkatheter (11) aufschiebbar ist und den Ballon (12) zumindest teilweise übergreift,

- daß sich das Kopfsegment (16) des Manschettenkatheters durch Aufblasen des Ballons (12) bis zur Anlage an der Innenwand des Gefäßes aufweiten läßt,

- und daß das über die Außenlumina (18) zugeführte bzw. eingefüllte Fluid mit Hilfe eines angelegten Drucks durch die Außenöffnungen (24) in das Gefäß bzw. die Gefäßwand applizierbar ist.

2. Manschettenkatheter nach Anspruch 1,
dadurch gekennzeichnet,
daß die Austrittsöffnungen (24) präformiert sind und sich durch die Applikation des Ballondrucks öffnen.

3. Manschettenkatheter nach Anspruch 1,
dadurch gekennzeichnet,
daß die Austrittsöffnungen (24) präformiert sind und sich durch die Applikation eines zusätzlichen Drucks auf die Außenlumina (18) öffnen.

* C L M S *

4. Manschettenkatheter nach einem der Ansprüche 1 bis 3,
dadurch gekennzeichnet,
daß das Kopfsegment (16) auf der Außenseite zwischen den Austrittsöffnungen (24) mit in Längsrichtung verlaufenden Radialeinschnitten (22) versehen ist.

5. Manschettenkatheter nach Anspruch 4,
dadurch gekennzeichnet,
daß auch auf der das zentrale Lumen (20) begrenzenden Innenwand zwischen den Außenlumina (18) in Längsrichtung verlaufende Radialeinschnitte (23) vorhanden sind.

6. Manschettenkatheter nach einem oder mehreren der Ansprüche 1 bis 5,
dadurch gekennzeichnet,
daß die Präformation der Austrittsöffnungen (24) derart ausgeführt ist, daß sich die Austrittsöffnungen mit ansteigendem Druck vom distalen Ende ausgehend zum proximalen Ende des Kopfsegmentes (16) hin verlaufend öffnen.

7. Manschettenkatheter nach einem oder mehreren der Ansprüche 1 bis 6,
dadurch gekennzeichnet,
daß über den Umfang des Kopfsegmentes (16) zwischen sechs bis zwanzig Außenlumina (18) vorgesehen sind.

* C L M S *

ZUSAMMENFASSUNG

MANSCHETTENKATHETER

Ein Manschettenkatheter (10) mit einem zentralen Lumen (20) weist auf seinem Umfang einen Kranz von Außenlumina (18) auf, die im Kopfsegment (16) in Austrittsöffnungen (24) enden. Der Manschettenkatheter wird mit seinem zentralen Lumen auf einen Ballonkatheter (11) aufgeschoben, so daß sich das Kopfsegment (16) durch Aufblasen des Ballons (12) bis zur Anlage an der Innenwand des Gefäßes aufweiten läßt. Das über die Außenlumina (18) zugeführte bzw. in diese eingefüllte Fluid wird mit Hilfe eines angelegten Drucks durch die Austrittsöffnungen (24) in das Gefäß bzw. die Gefäßwand appliziert. Damit lassen sich Medikamente in einfacher Weise von außerhalb des Körpers an einen eng begrenzten Zielraum transportieren

(Fig. 1)

This Sheet Has Been Replaced

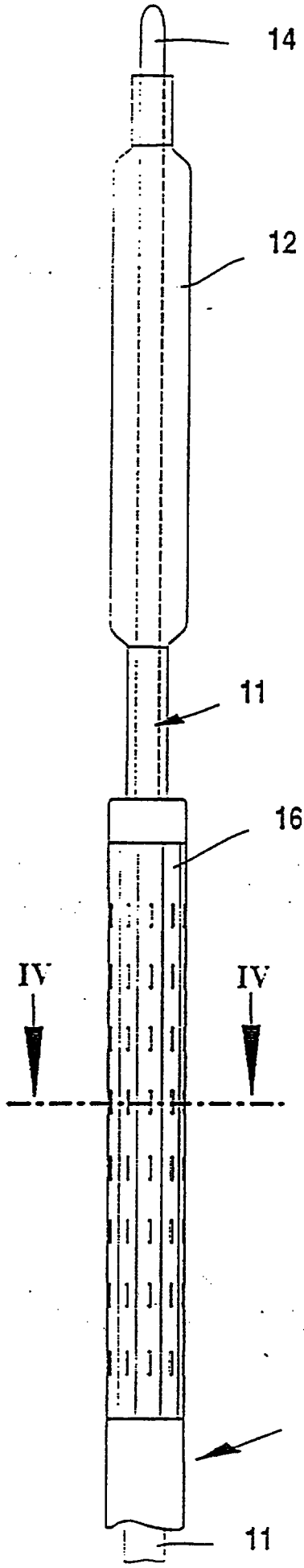


Fig. 1

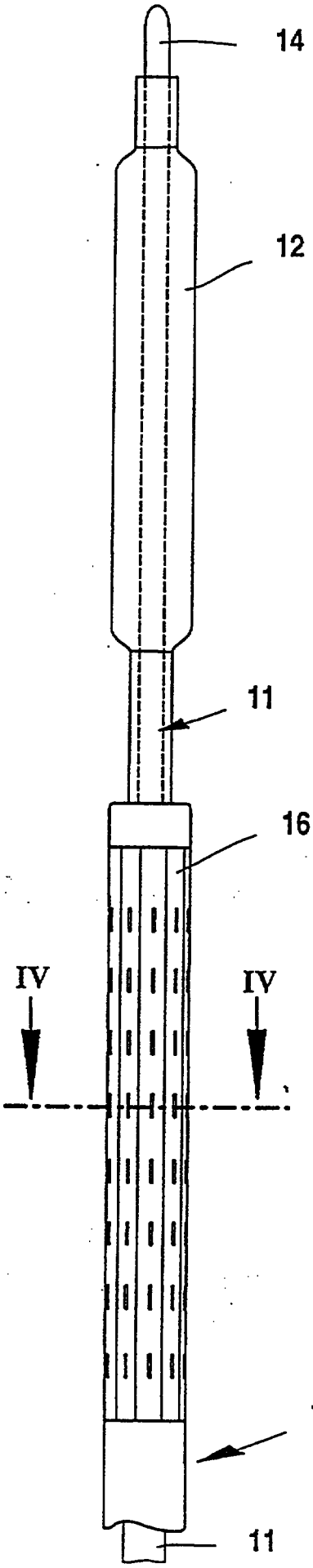


Fig. 1

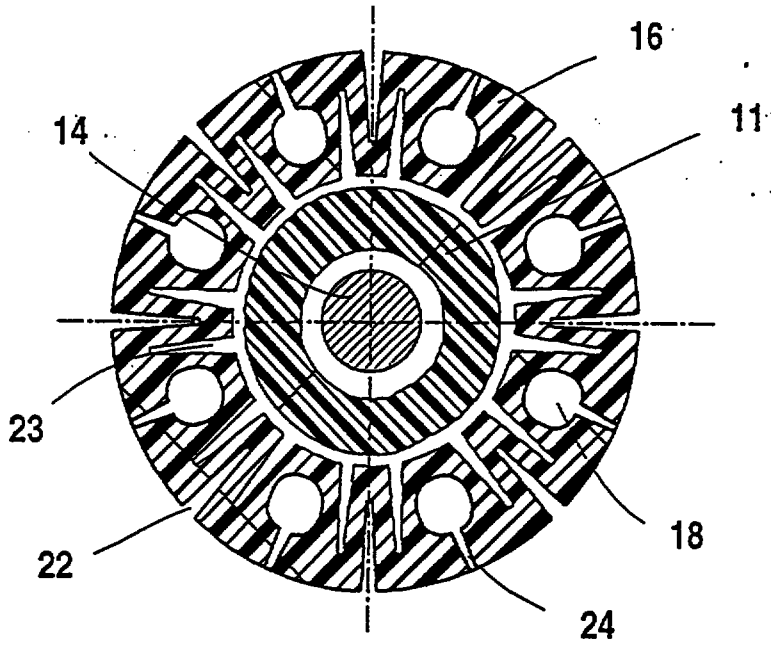


Fig. 4

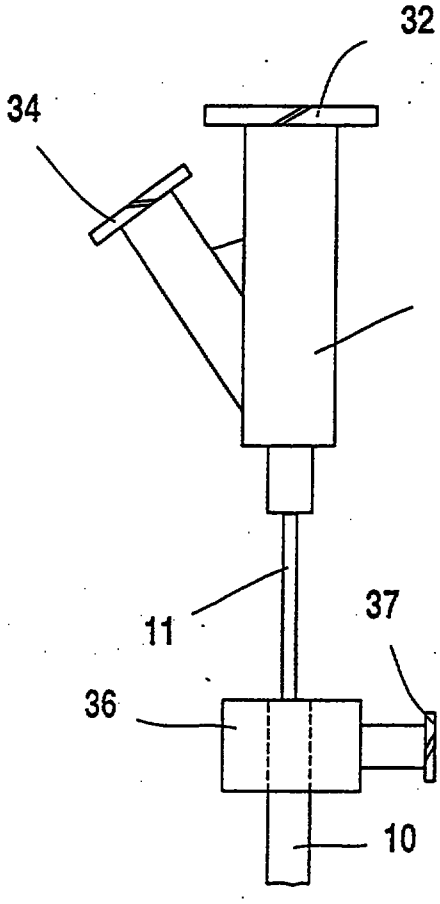


Fig. 5

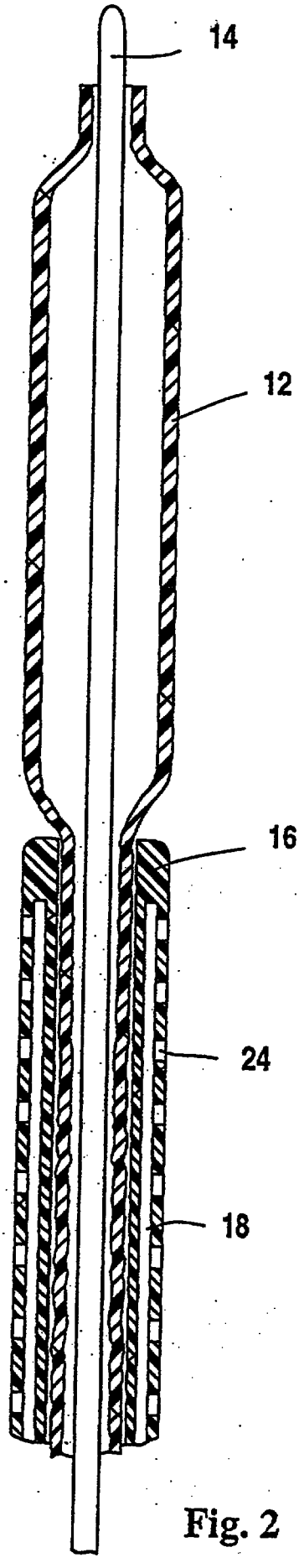


Fig. 2

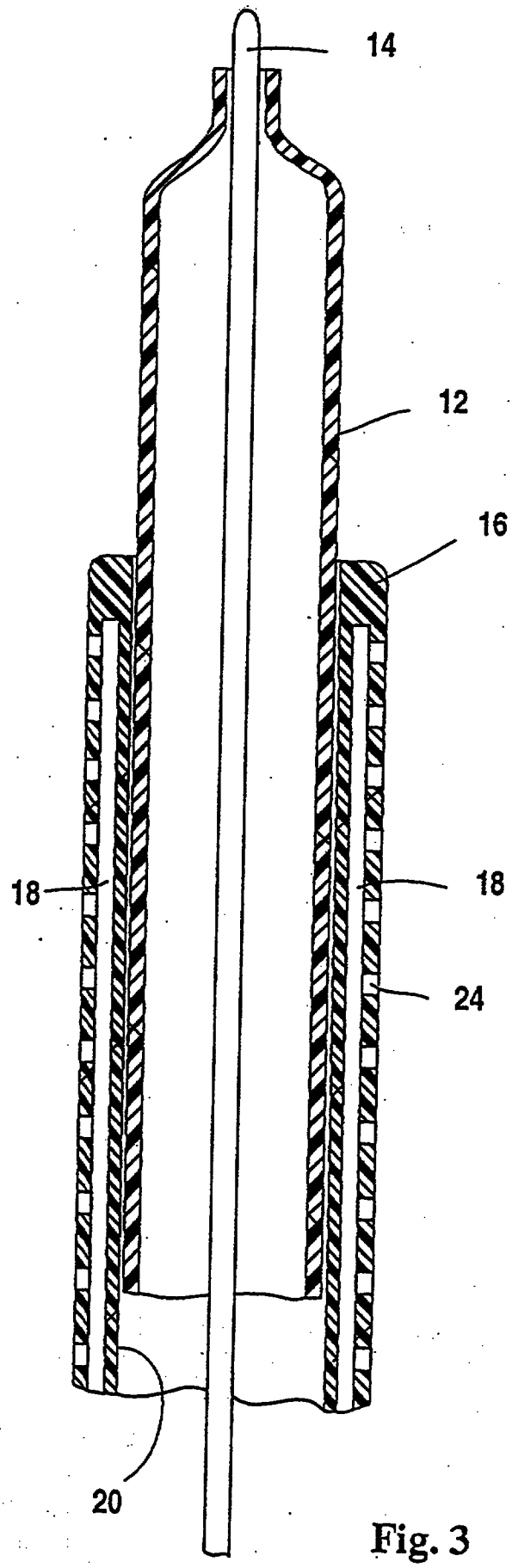


Fig. 3

REPLACED SHEETS SG
☑ Description : paged 1 to paged 8
☑ Claim(s) : paged 9 to paged 10
☑ Drawing(s) : paged 1/3 to paged 3/3
☑ Abstract : paged — to paged —

REPLACEMENT SHEETS SG
☑ Description : paged 1 to paged 8
☑ Claim(s) : paged 9 to paged 10
☑ Drawing(s) : paged 1/3 to paged 3/3
☑ Abstract : paged — to paged —
14 OCT 1996
DATE OF RECEIPT .....

SLEEVE CATHETER

The invention relates to a sleeve catheter for the wetting and infiltration of a vessel wall with a fluid particularly, medicine, preferably during routine treatment with a balloon catheter.

For the treatment of constricted passages in arteries, balloon dilation is recognized as an only little invasive but very effective and elegant method. Experience however shows that this treatment method has a high recurrence rate in the order of about 30% of the treated patients, that is, within a period of several months, for example, between 3 and 6 months, passage constriction will reoccur. It has been shown that this is at least partly caused by cell growth which is caused by the balloon dilation, that is, by expansion and rupture of the tissue. It is therefore desirable to provide for the vessel area which is subjected to such balloon dilation additional treatment which counteracts such tissue growth.

Various methods for growth-inhibiting treatment are known, particularly, the application of energy, for example, by means of a laser or the localized treatment with special medicine. As carrier for the localized treatment with medicine it is known to use wire wall supports (so-called stents) whose use however is complicated and which cannot be removed.

This is the replacement sheet

Date: 14/10/96

It has also been proposed to use balloon catheters with perforated balloons so that, during the dilation procedure, medication can be administered for penetration into the tissue. However, this proposal was found to be unsuitable since already at the beginning of, and during, balloon expansion, uncontrollable amounts of medicine are lost so that it becomes impossible to apply a defined amount of medicine to the tissue wall areas to be treated for wetting of the tissue and infiltration into the tissue wall. During inflation of the balloon, that is, before the balloon wall abuts the vessel wall, a substantial amount of the medicine is released and this prematurely released amount of medicine does not reach the vessel layers to be treated and, consequently, an undesirably high dosage is required if the particular vessel area to be treated is to be exposed to a sufficient amount of medicine. Another disadvantage is seen in the fact that only an insufficient amount of pressure can be generated with a perforated balloon which may not be enough to expand the restricted vessel area.

It is desirable to overcome the disadvantages as described in connection with a perforated balloon, wherein however the effectiveness and the elegance of balloon dilation should be maintained and medication treatment of the tissue and the vessel wall should be facilitated during the same procedure without essential additional time input. It is therefore the object of the invention to improve the established balloon catheter procedure such that, on one hand, the high recurrence rate can be reduced by the simultaneous administration of medicine, and, on the other hand, the medicine is administered in the desired dosage and is applied essentially only to the tissue areas to be treated.

In a sleeve catheter for supplying medicine to the walls of a vessel or tubular organ in which a number of outer lumina extend longitudinally around a central

This is the replacement sheet

Date: 14|10|96

lumen, the outer lumina have radial discharge openings in the area of the head portion of the catheter, which is slidable onto a balloon catheter in order to be disposed at least partially on the balloon of the balloon catheter so as to be expandable thereby into abutment with the inner wall of a vessel to be dilated whereby medicine can be supplied through the discharge openings in the outer lumina under pressure directly to the tissue of the vessel adjacent the outer lumina, thereby applying the medicine solely to the area engaged by the outer surface of the head portion.

The arrangement according to the invention has the advantage that the sleeve catheter is slidable onto a portion of the deflated balloon of a balloon catheter, so that the low balloon profile as required for the insertion of the catheter into constricted vessel area is essentially maintained. Inflation of the balloon forces the head portion of the sleeve catheter into engagement with the tissue to be treated so that, during the dilation procedure the medicine can be applied, under pressure, through the outer lumina directly to the tissue to be treated whereby it enters solely this tissue. In this manner all toxic compounds or gene-technologically designated medicine adapted to inhibit undesirable cell growth in the treated area can be injected directly and only into the tissue area to be treated.

In a further embodiment according to the invention the perforations are preformed such that they are opened by application of the balloon pressure. They may also be preformed in such a manner that they are opened by the application of additional pressure to the outer lumina.

In order to facilitate the expansion of the head portion of the sleeve catheter, in another embodiment, the head portion is provided at its outside between the discharge openings with longitudinally extending radial notches. Expansion can be further facilitated by

This is the replacement sheet

Date: 14/10/96

providing longitudinally extending radial notches also in the inner wall, between the outer lumina, which is disposed adjacent the inner lumen of the catheter.

In order to administer the medicine as locally as possible, that is, only in the close proximity of the constricted vessel area, or stenosis, it is advantageous if the discharge openings are preformed in such a manner that they are opened gradually with increasing pressure, beginning at the distal end, toward the proximal end of the head portion. Depending on the location where the sleeve catheter is to be used in connection with a balloon catheter, in vessels or in organs, it may be advantageous to administer different amounts of medicine for wetting the tissue or infiltration into the tissue. It is therefore within the scope of the present invention to provide distributed over the circumference of the head portion, six to twenty outer lumina.

The advantages and features of the invention are apparent from the following description of an embodiment described below with reference to the drawings and defined in the claims.

Figure 1 shows the head portion of a sleeve catheter disposed on a balloon catheter;

Fig. 2 is a cross-sectional view of the front end of the balloon catheter with the head portion of the sleeve catheter disposed thereon;

Fig. 3 is a cross-sectional view of the inflated balloon with an expanded head portion of the sleeve catheter,

Fig. 4 is a cross-sectional view along lines IV-IV of Fig. 1; and

Fig. 5 shows the connecting structure for the operation of the balloon catheter and the sleeve catheter.

This is the replacement sheet

Date: 14/10/96

Figs. 1, 2 and 3 show the details of a sleeve catheter 10 disposed on a balloon catheter 11. The sleeve catheter is slipped onto the balloon catheter such that the head portion 16 extends at least partially over the balloon 12 which is mounted on a flexible guide rod 14 as shown in Fig. 2. In these relative positions the two catheters are inserted into a vessel or an organ. The outer lumina 18 terminate in the head portion of the sleeve catheter and they extend over the full length of the sleeve catheter up to the connecting structure which is shown in Fig. 5 and explained below. As shown the outer lumina 18 are arranged in a circle around a central lumen 20 wherein 6 to 20 outer lumina may be provided depending on the size and the application area of the sleeve catheter.

It is also possible to provide only one or two lumina which extend along the sleeve catheter and which are divided in the head portion into several outer lumina. The cross-section and the arrangement of the lumina are adapted to a particular application.

In the cross-sectional view of Fig. 4 which is taken across a head portion 16 disposed on a balloon catheter 11, there are eight outer lumina 18 which are provided with discharge openings 24 leading to the outside of the head portion. These discharge openings 24 are so designed that they open only toward the end of balloon pressure application and then discharge a medicine contained in the outer lumina 18. It is also possible to preform the discharge openings in such a way that they open only by application of additional pressure applied via the connecting structure.

In order to facilitate expansion of the head portion 16 it is provided, at least on the outside, with radial grooves 22 which extend longitudinally between the discharge openings 24 and to a limited depth spaced from the inner wall of the head portion so as to provide for a

This is the replacement sheet

Date: 14/10/96

hinge structure allowing the radial grooves 22 to open up and expand the head portion with only small pressure requirements. In order to further reduce the pressure required for the expansion of the head portion further radial grooves 23 may be provided at the inside of the head portion adjacent the central lumen 20, the grooves 23 extending longitudinally between the outer lumina 18. If two radial grooves 23 are provided at opposite sides of a radial groove 22, three-hinge structures are formed which further facilitate expansion of the head portion.

With this arrangement the head portion can be pressed in sufficiently tight contact with the vessel walls by the pressure of, for example, 5 to 8 bar required for full expansion of the balloon so that the medicine, when applied through the outer lumina 18 and the discharge openings 24, will not flow away but will be applied to the inner wall surface in a highly localized fashion such that it will penetrate the wall and then infiltrate the inner layers in sufficiently high concentrations.

For good distribution of the medicine during dilation when the head portion is firmly pressed against the expanded tissue by the pressure built up in the inner balloon, that is, in order to inject the medicine essentially in the center area of the constriction being treated, the discharge openings 24 are preferably preformed in such a manner that they open with increasing pressure beginning at the distal end of the head portion toward the proximal end. With this arrangement it is insured that the injected medicine is not carried away but is applied in sufficiently high concentration to the tissue layers as desired and subsequently infiltrates into the deeper wall layers. The amount of medicine released into the vessel after deflation of the catheter which normally takes place after about 60 seconds is then relatively small and it is diluted in a material way so that as far as the dose is concerned it is irrelevant for

This is the replacement sheet

Date: 14/10/96

the total body system even if a large dose was applied localized to the treated vessel area. For application, primarily already well known cell-toxic compounds are used whose effects can be well determined but also genetically designed medicine may be used.

Utilization of pressure generators (indeflator) as normally used in connection with balloon dilation permits injection and infiltration of medicine into the tissue under any desired pressure and in any desired predetermined amount.

Fig. 5 shows a connecting structure for an indeflator and for an operating mechanism for injecting a medicine. The connecting structure comprises a Y connector with a terminal 32 for scavenging and a terminal 34 for the indeflator. The balloon catheter 11 is connected to this Y connector. The sleeve catheter 10 which surrounds the balloon catheter 11 is provided at its rear end with a connecting structure 36 which has a terminal 37 through which the medicine is supplied by means of a pressurizer which is not shown in the drawing. Within the connecting structure 36 the terminal 37 is connected to the outer lumina 18 of the sleeve catheter.

With this connecting structure arrangement the balloon dilation can be performed independently of the application of the medicine so that the medicine can be administered independently and in predetermined amounts.

For the treatment of coronary vessels the invention provides for a substantial advantage in that the elegance of the balloon dilation method is maintained and the procedure is not extended because the medicine is injected during the normal dilation procedure during which, furthermore, an exactly defined amount of medicine is administered within a well determined vessel area.

However the arrangement according to the invention is suitable not only for treatment of coronary vessels but also for kidney vessels and vessels in extremities and, depending on the conditions, also for vessels

This is the replacement sheet

Date: 14/10/96

in the head of a patient. It may also be used for the wetting and infiltration of growth-inhibiting compounds in vessel portions of organs or tubular systems such as the urethra or the bile duct or other vessel-like organs. The arrangement according to the invention is also particularly well suited for the treatment of cancerous areas with growth-inhibiting compounds (in this case cytostatics). The arrangement further permits treatment of tubular structures riddled with carcinoma without endangering or blocking passage therethrough that is also malicious sicknesses in the area of the trachea or the intestines can be treated in accordance with the invention without disturbing passage through the affected areas. Also for the treatment of prostate hypertrophy medicine can be administered in the described manner.

This is the replacement sheet

Date: 14/10/96

What is claimed is:

1. A sleeve catheter for the wetting and infiltration of a vessel wall or other tubular organ by a fluid, particularly a liquid medicine,
characterized in that

said sleeve catheter (10) comprises a head portion (16) with a central lumen (20) and a number of outer lumina (18) extending in cross section in a circle around said central lumen, each having discharge openings (24) formed in the head portion (16) thereof,

said sleeve catheter (10) is adapted to be slidable with its central lumen (20) onto a balloon catheter (11), so as to be disposed at least partially on the balloon of said balloon catheter,

said portion (16) of said sleeve catheter is expandable for engaging the inner wall of a vessel to be expanded upon inflation of said balloon (12), and

said fluid is supplied to said outer lumina (18) under pressure so as to be applied to said vessel wall via said discharge openings (24) when said head portion is in engagement with the inner wall of the vessel wall to be treated.

2. A sleeve catheter according to claim 1,
characterized in that

said discharge openings (24) are perforated such that they open by the application of the balloon pressure.

* C L M S *

This is the replacement sheet

Date: 14/10/96

3. A sleeve catheter according to claim 1,
characterized in that
said discharge openings (24) are preformed such that they are opened by the application of an additional pressure to the outer lumina (18).

4. A sleeve catheter according to any one of claims 1 to 3,
characteriozed in that
said head portion (16) includes, at its outside, longitudinally extending radial grooves (22) arranged between said discharge openings.

5. A sleeve catheter according to claim 4,
characterized in that
longitudinally extending radial grooves (23) are provided between said outer lumina (18) also in the inner wall of said lead portion adjacentto the central lumen (20).

6. A sleeve catheter according to one or more of claims 1 to 5,
characterized in that
said discharge openings (24) are preformed in such a way that they are opened successively with increasing pressure beginning at the distal end of the head portion and continuing toward the proximal end of the head portion (16).

7. A sleeve catheter according to one or more of claims 1 to 6,
characterized in that
said head portion (16) includes six to twenty outer lumina (18) distributed over its circumference.

* C L M S *

This is the replacement sheet

Date: 14/10/96

SLEEVE CATHETER

Abstract of the Disclosure

In a sleeve catheter (10) for supplying medicine to the walls of a vessel or tubular organ in which a number of outer lumina (18) extend longitudinally around a central lumen, the outer lumina have radial discharge openings (24). The area of the head portion (16) of the catheter which is slidable onto a balloon catheter (11) is expandable to thereby abut with the inner wall of a vessel. The fluid can be supplied through the discharge openings (24) in the outer lumina under pressure directly to the tissue of the vessel adjacent the outer lumina. Thereby medicine can be applied easily to a limited area inside the body.

(Fig. 1)

This is the **replacement sheet**

Date: 14/10/96

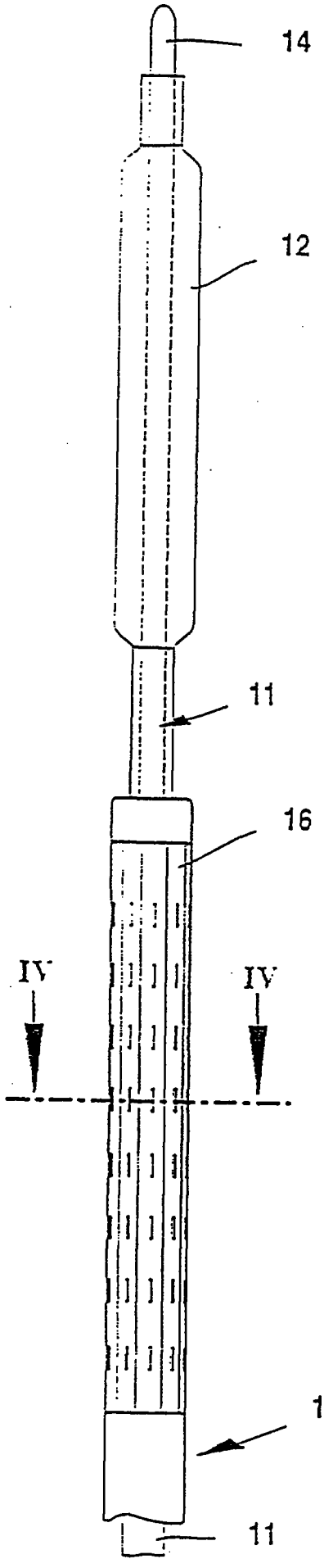


Fig. 1

This is the replacement sheet

Date: 14/10/96

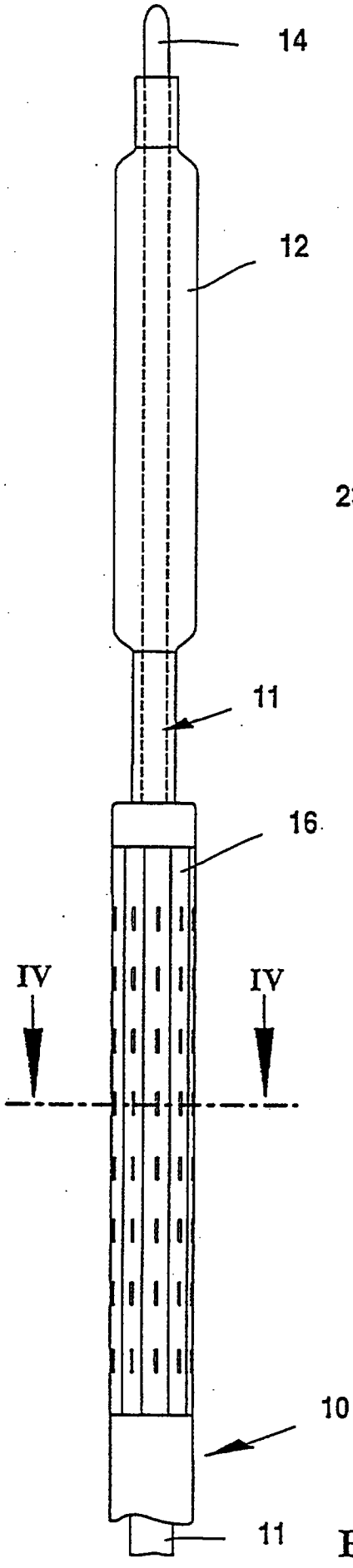


Fig. 1

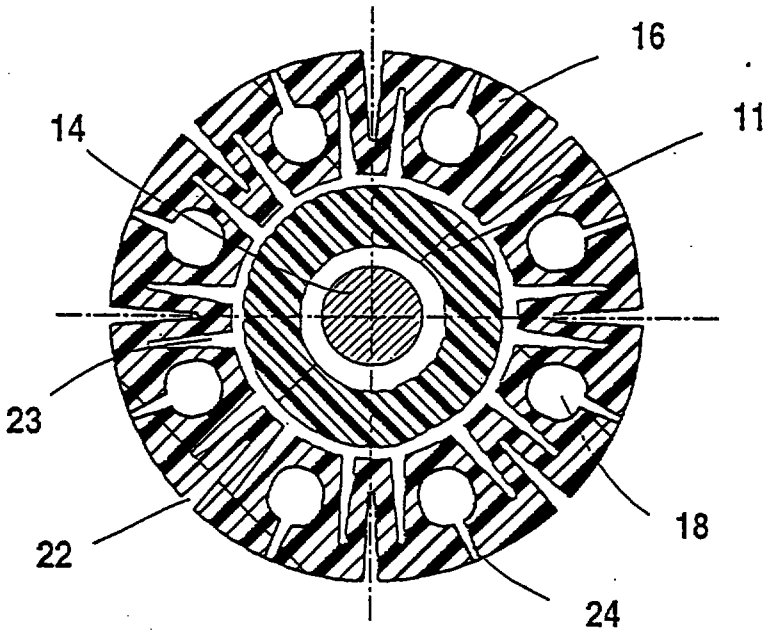


Fig. 4

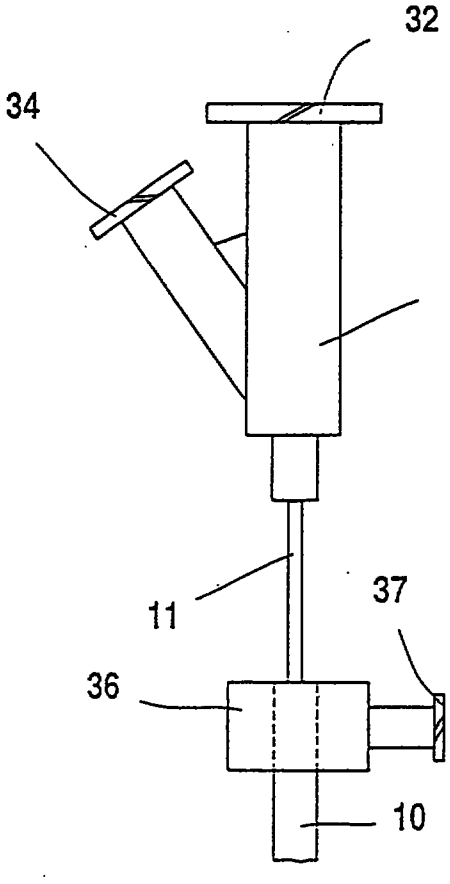


Fig. 5

This is the replacement sheet

Date: 14/10/96

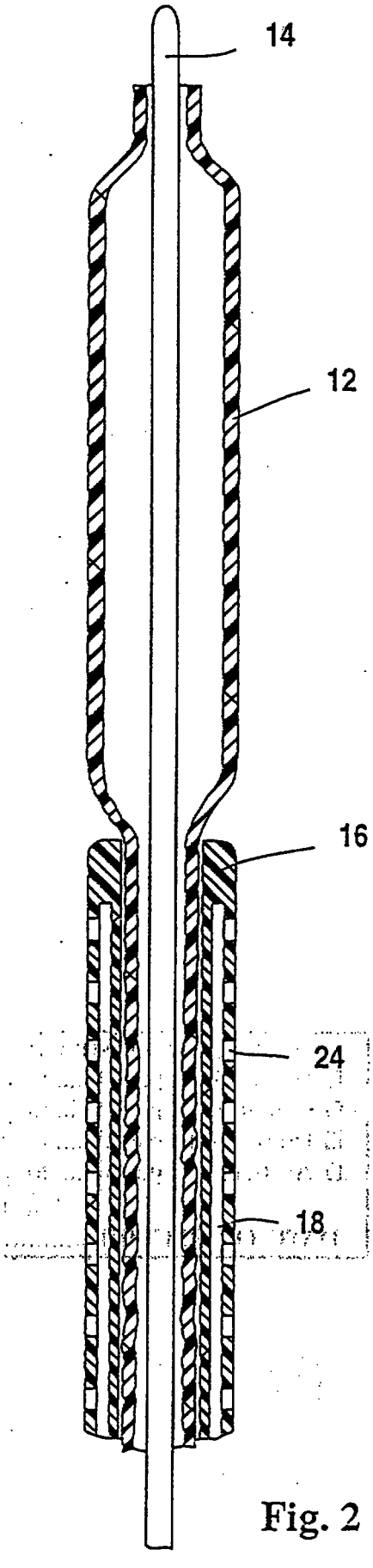


Fig. 2

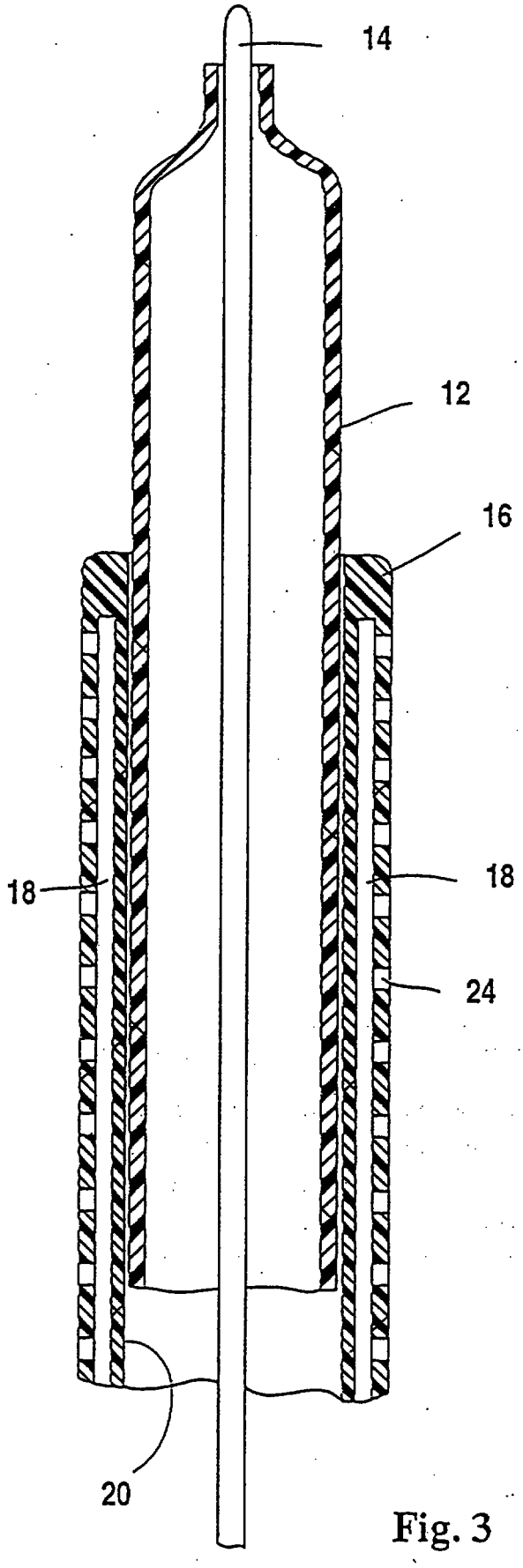


Fig. 3

This is the replacement sheet

Date: 14/10/96

REPLACEMENT SHEETS SG 8
☐ Description : paged 1 to paged 9
☐ Claim(s) : paged 10 to paged 10
☐ Drawing(s) : paged 1/3 to paged 3/3
☐ Abstract : paged 11 to paged —
14 APR 1997
DATE OF RECEIPT .....

1

SLEEVE CATHETER

The invention relates to a sleeve catheter for the wetting and infiltration of a vessel wall with a fluid particularly, medicine, preferably during routine treatment with a balloon catheter.

For the treatment of constricted passages in arteries, balloon dilation is recognized as an only little invasive but very effective and elegant method. Experience however shows that this treatment method has a high recurrence rate in the order of about 30% of the treated patients, that is, within a period of several months, for example, between 3 and 6 months, passage constriction will reoccur. It has been shown that this is at least partly caused by cell growth which is caused by the balloon dilation, that is, by expansion and rupture of the tissue. It is therefore desirable to provide for the vessel area which is subjected to such balloon dilation additional treatment which counteracts such tissue growth.

Various methods for growth-inhibiting treatment are known, particularly, the application of energy, for example, by means of a laser or the localized treatment with special medicine. As carrier for the localized treatment with medicine it is known to use wire wall supports (so-called stents) whose use however is complicated and which cannot be removed.

This is the replacement sheet

Date: 14/4/97

It has also been proposed to use balloon catheters with perforated balloons so that, during the dilation procedure, medication can be administered for penetration into the tissue. However, this proposal was found to be unsuitable since already at the beginning of, and during, balloon expansion, uncontrollable amounts of medicine are lost so that it becomes impossible to apply a defined amount of medicine to the tissue wall areas to be treated for wetting of the tissue and infiltration into the tissue wall. During inflation of the balloon, that is, before the balloon wall abuts the vessel wall, a substantial amount of the medicine is released and this prematurely released amount of medicine does not reach the vessel layers to be treated and, consequently, an undesirably high dosage is required if the particular vessel area to be treated is to be exposed to a sufficient amount of medicine. Another disadvantage is seen in the fact that only an insufficient amount of pressure can be generated with a perforated balloon which may not be enough to expand the restricted vessel area.

It is desirable to overcome the disadvantages as described in connection with a perforated balloon, wherein however the effectiveness and the elegance of balloon dilation should be maintained and medication treatment of the tissue and the vessel wall should be facilitated during the same procedure without essential additional time input. It is therefore the object of the invention to improve the established balloon catheter procedure such that, on one hand, the high recurrence rate can be reduced by the simultaneous administration of medicine, and , on the other hand, the medicine is administered in the desired dosage and is applied essentially only to the tissue areas to be treated.

In a sleeve catheter for supplying medicine to the walls of a vessel or tubular organ in which a number of outer lumina extend longitudinally around a central

This is the replacement sheet

Date: 14/4/97

lumen, the outer lumina have radial discharge openings in the area of the head portion of the catheter, which is slidable onto a balloon catheter in order to be disposed at least partially on the balloon of the balloon catheter so as to be expandable thereby into abutment with the inner wall of a vessel to be dilated whereby medicine can be supplied through the discharge openings in the outer lumina under pressure directly to the tissue of the vessel adjacent the outer lumina, thereby applying the medicine solely to the area engaged by the outer surface of the head portion.

The arrangement according to the invention has the advantage that the sleeve catheter is slidable onto a portion of the deflated balloon of a balloon catheter, so that the low balloon profile as required for the insertion of the catheter into constricted vessel area is essentially maintained. Inflation of the balloon forces the head portion of the sleeve catheter into engagement with the tissue to be treated so that, during the dilation procedure the medicine can be applied, under pressure, through the outer lumina directly to the tissue to be treated whereby it enters solely this tissue. In this manner all toxic compounds or gene-technologically designated medicine adapted to inhibit undesirable cell growth in the treated area can be injected directly and only into the tissue area to be treated.

In a further embodiment according to the invention the perforations are preformed such that they are opened by application of the balloon pressure. They may also be preformed in such a manner that they are opened by the application of additional pressure to the outer lumina.

In order to facilitate the expansion of the head portion of the sleeve catheter, in another embodiment, the head portion is provided at its outside between the discharge openings with longitudinally extending radial notches. Expansion can be further facilitated by

This is the replacement sheet

Date: 14/4/97

providing longitudinally extending radial notches also in the inner wall, between the outer lumina, which is disposed adjacent the inner lumen of the catheter.

In order to administer the medicine as locally as possible, that is, only in the close proximity of the constricted vessel area, or stenosis, it is advantageous if the discharge openings are preformed in such a manner that they are opened gradually with increasing pressure, beginning at the distal end, toward the proximal end of the head portion. Depending on the location where the sleeve catheter is to be used in connection with a balloon catheter, in vessels or in organs, it may be advantageous to administer different amounts of medicine for wetting the tissue or infiltration into the tissue. It is therefore within the scope of the present invention to provide distributed over the circumference of the head portion, six to twenty outer lumina.

The advantages and features of the invention are apparent from the following description of an embodiment described below with reference to the drawings and defined in the claims.

Figure 1 shows the head portion of a sleeve catheter disposed on a balloon catheter;

Fig. 2 is a cross-sectional view of the front end of the balloon catheter with the head portion of the sleeve catheter disposed thereon;

Fig. 3 is a cross-sectional view of the inflated balloon with an expanded head portion of the sleeve catheter;

Fig. 4 is a cross-sectional view along lines IV-IV of Fig. 1; and

Fig. 5 shows the connecting structure for the operation of the balloon catheter and the sleeve catheter.

This is the replacement sheet

Date: 14/4/97

Figs. 1, 2 and 3 show the details of a sleeve catheter 10 disposed on a balloon catheter 11. The sleeve catheter is slipped onto the balloon catheter such that the head portion 16 extends at least partially over the balloon 12 which is mounted on a flexible guide rod 14 as shown in Fig. 2. In these relative positions the two catheters are inserted into a vessel or an organ. The outer lumina 18 terminate in the head portion of the sleeve catheter and they extend over the full length of the sleeve catheter up to the connecting structure which is shown in Fig. 5 and explained below. As shown the outer lumina 18 are arranged in a circle around a central lumen 20 wherein 6 to 20 outer lumina may be provided depending on the size and the application area of the sleeve catheter.

It is also possible to provide only one or two lumina which extend along the sleeve catheter and which are divided in the head portion into several outer lumina. The cross-section and the arrangement of the lumina are adapted to a particular application.

In the cross-sectional view of Fig. 4 which is taken across a head portion 16 disposed on a balloon catheter 11, there are eight outer lumina 18 which are provided with discharge openings 24 leading to the outside of the head portion. These discharge openings 24 are so designed that they open only toward the end of balloon pressure application and then discharge a medicine contained in the outer lumina 18. It is also possible to preform the discharge openings in such a way that they open only by application of additional pressure applied via the connecting structure.

In order to facilitate expansion of the head portion 16 it is provided, at least on the outside, with radial grooves 22 which extend longitudinally between the discharge openings 24 and to a limited depth spaced from the inner wall of the head portion so as to provide for a

This is the replacement sheet

Date: 14/4/97

hinge structure allowing the radial grooves 22 to open up and expand the head portion with only small pressure requirements. In order to further reduce the pressure required for the expansion of the head portion further radial grooves 23 may be provided at the inside of the head portion adjacent the central lumen 20, the grooves 23 extending longitudinally between the outer lumina 18. If two radial grooves 23 are provided at opposite sides of a radial groove 22, three-hinge structures are formed which further facilitate expansion of the head portion.

With this arrangement the head portion can be pressed in sufficiently tight contact with the vessel walls by the pressure of, for example, 5 to 8 bar required for full expansion of the balloon so that the medicine, when applied through the outer lumina 18 and the discharge openings 24, will not flow away but will be applied to the inner wall surface in a highly localized fashion such that it will penetrate the wall and then infiltrate the inner layers in sufficiently high concentrations.

For good distribution of the medicine during dilation when the head portion is firmly pressed against the expanded tissue by the pressure built up in the inner balloon, that is, in order to inject the medicine essentially in the center area of the constriction being treated, the discharge openings 24 are preferably preformed in such a manner that they open with increasing pressure beginning at the distal end of the head portion toward the proximal end. With this arrangement it is insured that the injected medicine is not carried away but is applied in sufficiently high concentration to the tissue layers as desired and subsequently infiltrates into the deeper wall layers. The amount of medicine released into the vessel after deflation of the catheter which normally takes place after about 60 seconds is then relatively small and it is diluted in a material way so that as far as the dose is concerned it is irrelevant for

This is the replacement sheet

Date: 14/4/97

the total body system even if a large dose was applied localized to the treated vessel area. For application, primarily already well known cell-toxic compounds are used whose effects can be well determined but also genetically designed medicine may be used.

Utilization of pressure generators (indeflator) as normally used in connection with balloon dilation permits injection and infiltration of medicine into the tissue under any desired pressure and in any desired predetermined amount.

Fig. 5 shows a connecting structure for an indeflator and for an operating mechanism for injecting a medicine. The connecting structure comprises a Y connector with a terminal 32 for scavenging and a terminal 34 for the indeflator. The balloon catheter 11 is connected to this Y connector. The sleeve catheter 10 which surrounds the balloon catheter 11 is provided at its rear end with a connecting structure 36 which has a terminal 37 through which the medicine is supplied by means of a pressurizer which is not shown in the drawing. Within the connecting structure 36 the terminal 37 is connected to the outer lumina 18 of the sleeve catheter.

With this connecting structure arrangement the balloon dilation can be performed independently of the application of the medicine so that the medicine can be administered independently and in predetermined amounts.

For the treatment of coronary vessels the invention provides for a substantial advantage in that the elegance of the balloon dilation method is maintained and the procedure is not extended because the medicine is injected during the normal dilation procedure during which, furthermore, an exactly defined amount of medicine is administered within a well determined vessel area.

However the arrangement according to the invention is suitable not only for treatment of coronary vessels but also for kidney vessels and vessels in extremities and, depending on the conditions, also for vessels

This is the replacement sheet

Date: 14/4/97

in the head of a patient. It may also be used for the wetting and infiltration of growth-inhibiting compounds in vessel portions of organs or tubular systems such as the urethra or the bile duct or other vessel-like organs. The arrangement according to the invention is also particularly well suited for the treatment of cancerous areas with growth-inhibiting compounds (in this case cytostatics). The arrangement further permits treatment of tubular structures riddled with carcinoma without endangering or blacking passage therethrough that is also malicious sicknesses in the area of the trachea or the intestines can be treated in accordance with the invention without disturbing passage through the affected areas. Also for the treatment of prostate hypertrophy medicine can be administered in the described manner.

This is the replacement sheet

Date: 14/4/97

What is claimed is:

1. A sleeve catheter for the wetting and infiltration of a vessel wall or other tubular organ by a fluid, particularly a liquid medicine,
characterized in that

said sleeve catheter (10) comprises a head portion (16) with a central lumen (20) and a number of outer lumina (18) extending in cross section in a circle around said central lumen, each having discharge openings (24) formed in the head portion (16) thereof,

said sleeve catheter (10) is adapted to be slidable with its central lumen (20) onto a balloon catheter (11), so as to be disposed at least partially on the balloon of said balloon catheter,

said portion (16) of said sleeve catheter is expandable for engaging the inner wall of a vessel to be expanded upon inflation of said balloon (12), and

said fluid is supplied to said outer lumina (18) under pressure so as to be applied to said vessel wall via said discharge openings (24) when said head portion is in engagement with the inner wall of the vessel wall to be treated.

2. A sleeve catheter according to claim 1,
characterized in that

said discharge openings (24) are perforated such that they open by the application of the balloon pressure.

* C L M S *

This is the replacement sheet

Date: 14/4/97

3. A sleeve catheter according to claim 1,
characterized in that
said discharge openings (24) are preformed such that they are opened by the application of an additional pressure to the outer lumina (18).

4. A sleeve catheter according to any one of claims 1 to 3,
characteriozed in that
said head portion (16) includes, at its outside, longitudinally extending radial grooves (22) arranged between said discharge openings.

5. A sleeve catheter according to claim 4,
characterized in that
longitudinally extending radial grooves (23) are provided between said outer lumina (18) also in the inner wall of said lead portion adjacentto the central lumen (20).

6. A sleeve catheter according to one or more of claims 1 to 5,
characterized in that
said discharge openings (24) are preformed in such a way that they are opened successively with increasing pressure beginning at the distal end of the head portion and continuing toward the proximal end of the head portion (16).

7. A sleeve catheter according to one or more of claims 1 to 6,
characterized in that
said head portion (16) includes six to twenty outer lumina (18) distributed over its circumference.

* C L M S *

This is the replacement sheet

Date: 14/4/97

SLEEVE CATHETER

Abstract of the Disclosure

In a sleeve catheter (10) for supplying medicine to the walls of a vessel or tubular organ in with a number of outer lumina (18) extend longitudinally around a central lumen, the outer lumina have radial discharge openings (24). The area of the head portion (16) of the catheter which is slidable onto a balloon catheter (11) is expandable to thereby abut with the inner wall of a vessel. The fluid can be supplied through the discharge openings (24) in the outer lumina under pressure directly to the tissue of the vessel adjacent the outer lumina. Thereby medicine can be applied easily to a limited area inside the body.

(Fig. 1)

This is the replacement sheet

Date: 14/4/97

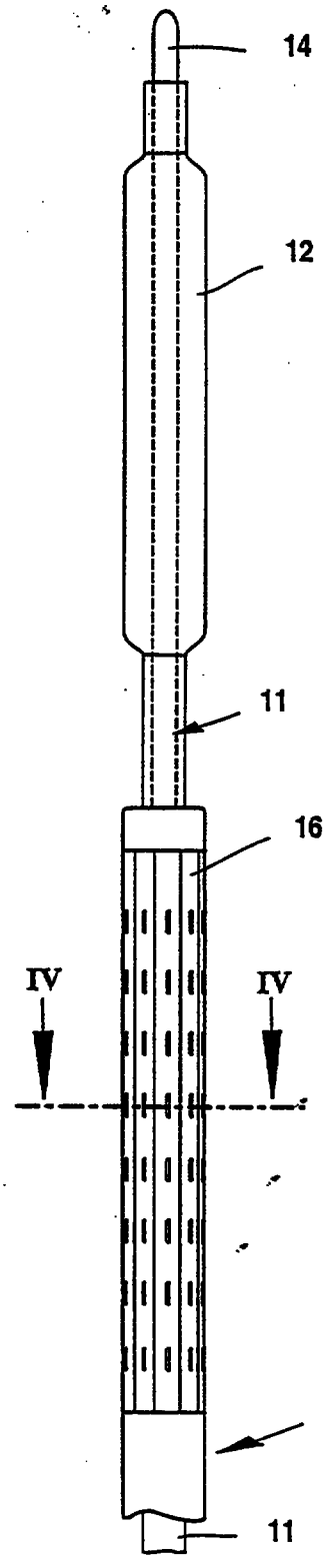


Fig. 1

This is the replacement sheet

Date: 14/4/97

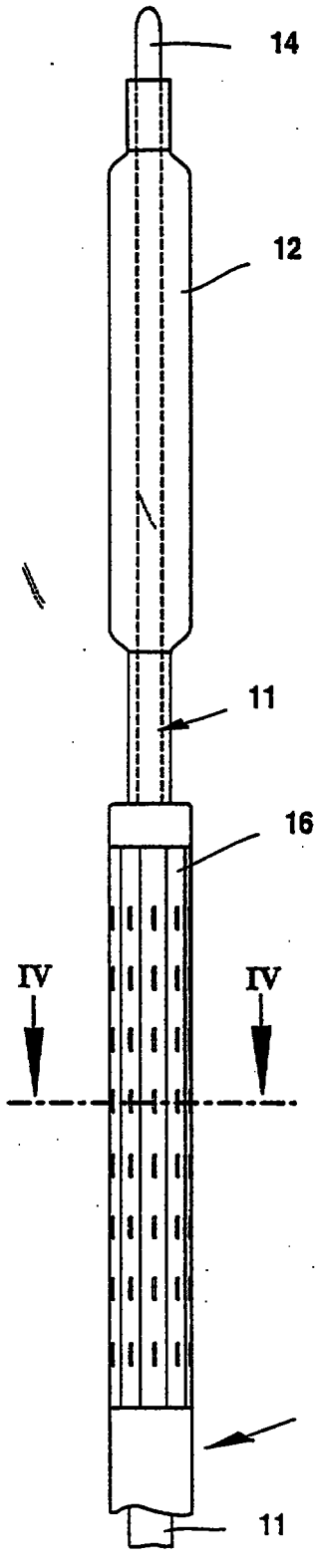


Fig. 1

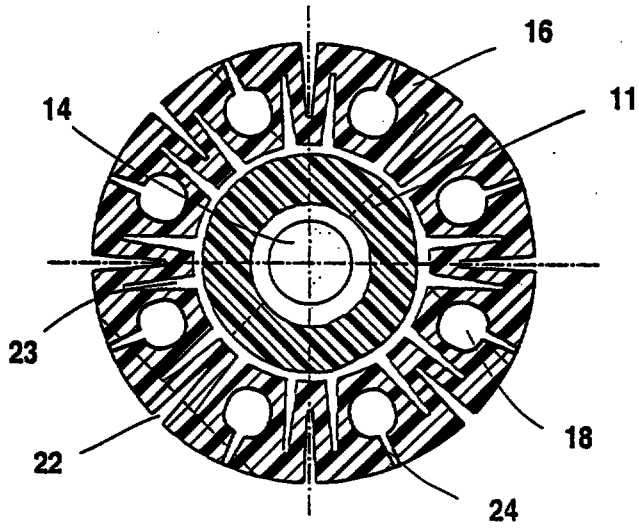


Fig. 4

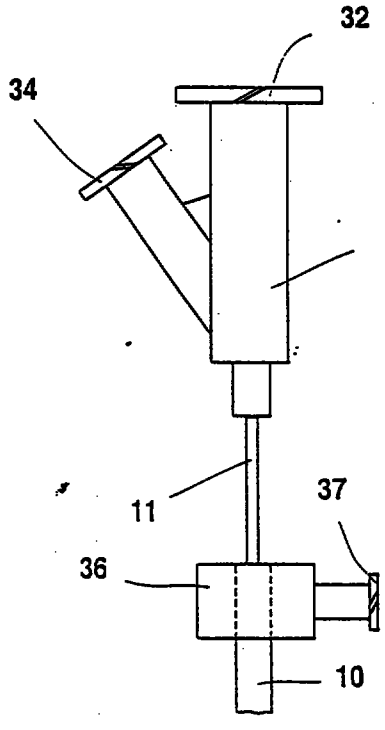


Fig. 5

This is the replacement sheet

Date: 14/4/97

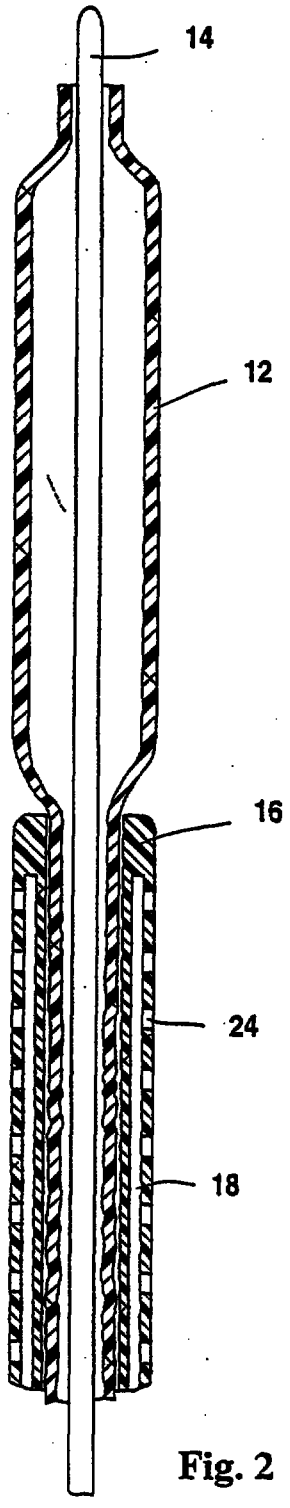


Fig. 2

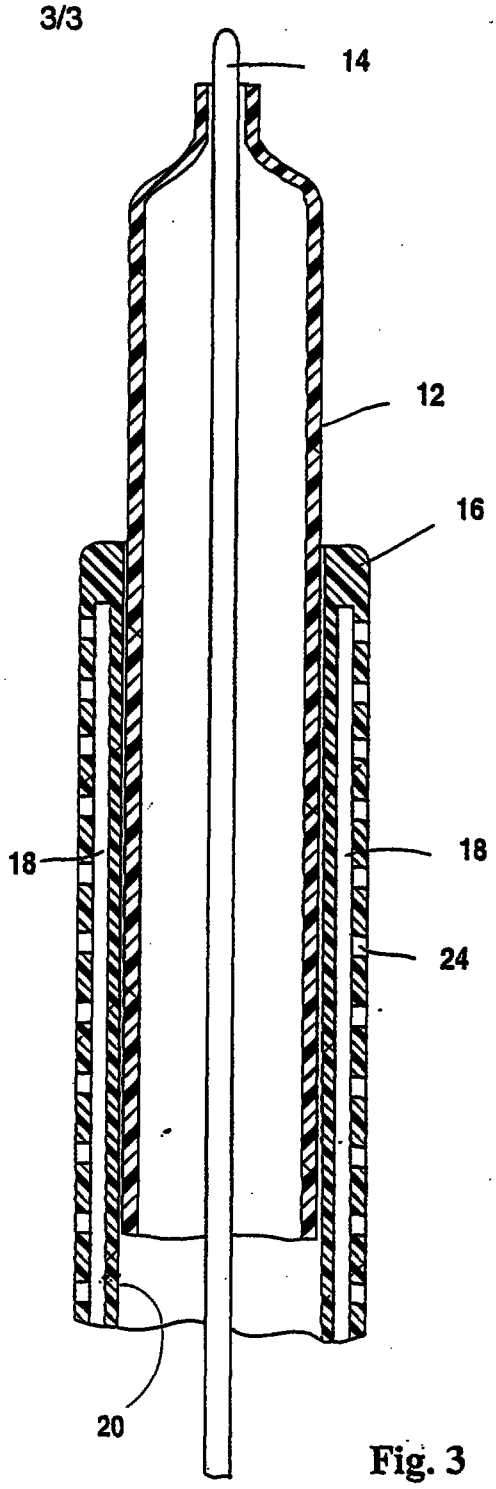


Fig. 3

This is the replacement sheet

Date: 14/4/97