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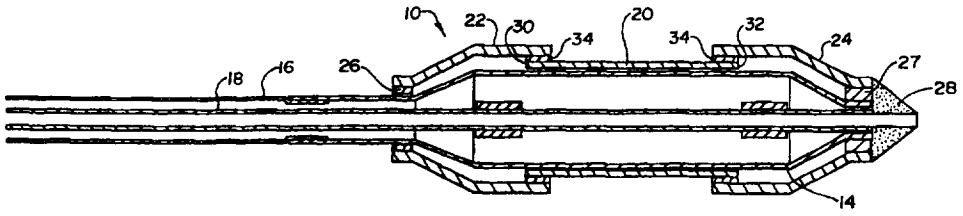

(57) Abstract

A stent delivery system (10) to facilitate introduction and placement of a stent, including a catheter having an expandable distal portion constructed and arranged for expanding the outer diameter of the catheter from a contracted state to an expanded state: a stent (20) positioned around the distal portion of the catheter having a contracted condition and being expandable to an expanded condition, and being sized in the contracted condition to closely surround the catheter in the contracted state, the expandable distal portion of the catheter including a balloon (14) within which there is included on the catheter shaft at least one body (22, 24) of a diameter larger than the catheter shaft to which the stent and balloon are fitted, as by crimping, for holding the stent in place until it is released therefrom by expansion of the balloon.

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STENT DELIVERY SYSTEM

This is a Continuation-In-Part application based on U.S. Serial No. 08/702,149 filed August 23, 1996, which is incorporated herein by reference in its entirety.

Background of the Invention

In typical PTCA procedures, a guiding catheter is percutaneously introduced into the cardiovascular system of a patient through a vessel and advanced through therein until the distal end thereof is at a desired location in the vasculature. A guidewire and a dilatation catheter having a balloon on the distal end thereof are introduced through the guiding catheter with the guidewire sliding through the dilatation catheter. The guidewire is first advanced out of the guiding catheter into the patient's coronary vasculature and the dilatation catheter is advanced over the previously advanced guidewire until the dilatation balloon is properly positioned across the lesion. Once in position across the lesion, the flexible, expandable, preformed balloon is inflated to a predetermined size with a liquid or gas at relatively high pressures, such as greater than about four atmospheres, to radially compress the arthrosclerotic plaque of the lesion against the inside of the artery wall and thereby dilate the lumen of the artery. The balloon is then deflated to a small profile so that the dilatation catheter may be withdrawn from the patients vasculature and blood flow resumed through the dilated artery.

In angioplasty procedures of the kind described above, there may be injury to or restenosis of the artery, which either necessitates another angioplasty procedure, a surgical by-pass operation, or some method of repairing or strengthening the area. To strengthen the area and help prevent restenosis, a physician can implant an intravascular prosthesis for maintaining vascular patency, commonly called a stent, inside the artery at the lesion. The stent is expanded to a larger diameter for placement in the vasculature, often by the balloon portion of the catheter. Stents delivered to a restricted coronary artery, expanded to a larger diameter by a balloon catheter, and left in place in the artery at the site of a dilated lesion are shown in U.S. Patent No. 4,740,207 to

Kreamer and U.S. Patent No. 5,007,926 to Derbyshire, the content of which is incorporated herein by reference. Palmaz et al., 156 *Radiology* 73 (1985) and U.S. Patent No. 4,733,665 describe introduction of a stent over a balloon catheter (incorporated herein by reference). A preferred stent for use with this invention is shown in PCT Application No. 960 3092 A1, published 8 February 1996, the content of which is incorporated herein by reference.

The present invention is particularly directed to improved arrangements for releasably covering the ends of the stent to prevent the stent ends from flaring and snagging to better facilitate delivery thereof.

The art referred to and/or described above is not intended to constitute an admission that any patent, publication or other information referred to herein is "prior art" with respect to this invention. In addition, this section should not be construed to mean that a search has been made or that no other pertinent information as defined in 37 C.F.R. §1.56(a) exists.

Summary of the Invention

This invention concerns apparatus suitable for delivery of stents to body cavities. In general, stents are prosthetic devices which can be positioned within a body cavity, for example, a blood vessel of the body of a living human or in some other difficultly accessible place. The stent prosthesis is formed of a generally tubular body, the diameter of which can be decreased or increased. Stents are particularly useful for permanently widening a vessel which is either in a narrowed state, or internally supporting a damaged vessel. Such stents are typically introduced into the body cavity by use of a catheter. The catheter is usually of the balloon catheter type in which the balloon is utilized to expand the stent, which is positioned over the balloon, to place it in a selected location in the body cavity. The present invention is particularly directed to improved arrangements for releasably covering/securing/attaching the stent, particularly the ends thereof, to the catheter to prevent snagging of the stent ends and to facilitate delivery thereof. The stent is held in place on the catheter and kept from flaring upward at its end(s) by means of at least one removable end covering means, or sock/sleeve, over the stent, the stent having been fitted to the catheter over the balloon, as by crimping.

Most specifically, this invention is directed to improved modifications to the subject matter of the Savin U.S. Patent No. 4,950,227 which is incorporated herein by reference.

In particular, the invention is directed to an improved stent delivery system designed to securely hold a stent over the balloon on a catheter, via the sleeve arrangements, and to protect the stent from deformation, damage or premature release during delivery intraluminally, as well as snagging during transportation. It is also a purpose of the present invention to provide for easier and smoother removal of the sleeve retaining means. The stent is formed to its lowest geometrical diameter when loaded. In one embodiment, rings or coils are placed over the ends of the stent to retain them and hold them to the balloon beneath the sleeves (unexpanded), and preferably adhered thereto, with little or no relative movement between the ID of the stent and the OD of the balloon/catheter arrangement. The sleeves aid in retaining the stent and hold the stent to the balloon (unexpanded). The rings or coils are each preferably attached (adhered) to the elastomeric socks and the other end of the sleeves are respectively attached to the catheter. Since most stents which are deformed to a low diameter will increase in diameter somewhat after being deformed (spring back), the rings/coils prevent spring back and increase the friction fit between the stent and balloon. When the balloon under the stent is inflated, the stent pushes out of the rings/coils and the sleeves are pushed down the balloon cones to allow the stent to deploy.

An alterative embodiment provides for easier and smoother removal of the sock retaining means. In this embodiment the rings or coils are placed over the cone portion of the balloon beneath the socks and preferably adhered thereto. The sleeves aid in retaining the stent and hold the stent to the balloon (unexpanded) with little or no relative movement between the ID of the stent and the OD of the balloon/catheter arrangement. The rings or coils are each preferably attached (adhered) to the elastomeric socks or sleeves. One end of the sleeves cover the ends of the stent and the other end of the sleeves are respectively attached to the catheter. When the balloon under the stent is inflated, the rings/coils, which are positioned on the tapered cone portion of the balloon, are driven primarily axially, resulting in the sleeves being pushed/pulled down the balloon cones to allow the stent to deploy. The positioning of the rings/coils on the cones of the balloon allows for more of an axial force when the balloon inflates rather

then a radial force which may be the case if the rings are positioned on the ends of the stent, which may have a flatter profile as apposed to the tapered profile of the cone portion. This allows for a steadier, smoother, more controlled removal of the sleeves. Since most stents which are deformed to a low diameter will increase in diameter somewhat after being deformed (spring back), the sleeves also somewhat prevent spring back and increase the friction fit between the stent and balloon.

In a different embodiment, a polymer tube may be formed into a spiral, as by cutting molding or extruding, except for about 1-2 mm on one end; its entire length need only be about 1-2 cm. The uncut portion of the spiral, i.e., the ring end is placed over the end of the stent to retain it as already described. The other end of the coil, a portion of which may be uncut also to form a ring is attached to the catheter.

Modifications to this embodiment include replacement of the plastic ring with a metal ring or coil and replacement of the sleeve/ring with a metal or plastic coil or coiled ribbon. Short balloon cone length and/or tension on the spiral can help the spiral move off the stent when the balloon is inflated.

Brief Description of the Figures

Figure 1 is a view, in longitudinal section, of the distal end portion of a balloon catheter having a stent fixed to the catheter by being crimped thereto over the balloon, the ends of the stent being held by a first embodiment of the invention;

Figure 2 is similar to Figure 1 in which the stent has been released;

Figure 3 is a view of a modification of the embodiment shown in Figures 1 and 2;

Figure 4 is a view of another modification to the embodiment of Figures 1 and 2;

Figure 5 is a showing of another embodiment of the invention used to hold the ends of the stent;

Figure 6 is a showing of the Figure 5 arrangement in which the stent has been released;

Figure 7 is a showing of yet another embodiment of the invention used to hold the ends of the stent;

Figure 8 is a showing of the Figure 7 arrangement in which the stent has been released;

Figure 9 is a view of an alternative embodiment, in longitudinal section, of the distal end portion of a balloon catheter having a stent fixed to the catheter by being crimped thereto over the balloon, the ends of the stent being covered by an alternate embodiment of the invention;

Figure 10 is similar to Figure 9 in which the stent has been released;

Figure 11 is a view of a modification of the embodiment shown in Figures 9 and 10;

Figure 12 is a view of another modification to the embodiment of Figures 9 and 10; and

Figures 13a-c are side views of various ring configurations.

Description of the Preferred Embodiments

Referring to Figures 1 and 2, a stent delivery system 10 includes a catheter such as an over-the-wire or rapid exchange. Balloon catheters are preferred herein as best examples of catheters having an expandable distal end portion constructed and arranged for expanding the outer diameter of the catheter from a contracted state to an expanded state. A balloon 14 is fixed to the distal end of the catheter by adhesive attachment of the proximal end to the outer shaft 16 of the catheter and the distal end to the inner shaft 18 of the catheter. Other arrangements known in the art may be used. Balloon 14 is shown in Figure 1 in its contracted state and in Figure 2 in its expanded state. A stent 20 is fixed about balloon 14 by two overlying retaining sleeves 22 and 24.

Various types of stents may be used with balloon expansion. For example, the stent may be a self-expanding stent which upon release self-expands and is further expanded or is merely aided in release by balloon expansion from the sleeves. Such stents may self-expand elastically or may be thermally induced such as stents formed of Nitinol or other shape memory metals or materials.

Any kind of stent may be delivered by the system of the invention, including plastically deformable or elastically deformable and they may be of any configuration or structure so long as they can be loaded at a low diameter and deployed

at a larger diameter, i.e., have a contracted condition and being expandable to an expanded condition of large diameter.

Stent 20 may be any of the various types known in the art, either balloon expandable or self-expandable. Exemplary stents are shown in U.S. Patent No. 4,735,665; U.S. Patent No. 4,950,227; EPO application No. 707 837 A1, and U.S. Patent No. 5,445,646. All of these patents are incorporated herein by reference and are intended to be exemplary only and not limiting. Various materials including stainless steel, tantalum, shape memory alloys and plastic may be used.

Stent 20 is radially compressed, as by crimping to a contracted condition, against balloon 14 to a relatively small loaded diameter having an OD of .044 inches for example, although it has a larger released diameter in the expanded condition.

Sleeves 22 and 24 may be formed of polyurethane tubing or the like, having for example an ID of .032-.038 inches and a wall thickness of .002-.004 inches, for example, and are axially fixed along catheter 10 to the proximal end of balloon 14 at 26 and to the distal end of balloon 14 at 27 by means of polyurethane adhesive. The distal end also includes a tapered end 28 which may be formed of the same adhesive.

The sleeves may be of an expandable material, preferably elastomers such as polyurethane, silicone, latex or polyether amide, by way of example only. The material should be formable into a thin walled tube. Only one sleeve may be provided at one end of the stent, preferably the distal end. However, the use of a pair of sleeves, one at each end of the stent, is most preferred.

Sleeves 22 and 24 overlap stent 20 at each of its ends 30 and 32, respectively. For example, the overlap may be 0.5-1.5 mm. Reinforcing rings 34 are included under the overlapping portions of sleeves 22 and 24 and in contact with the stent ends. The rings may be attached to the sleeves with adhesive such as a polyurethane adhesive. The rings may be plastic, such as polyimide or polyethylene, or metal, such as platinum, gold, stainless steel or Nitinol, and may be .001-.004 inches and the ID of the ring is to match the desired OD of the stent. The function of the rings is to compress the stent and hold it down.

Referring to Figure 2, in its expanded state balloon 14 has an enlarged diameter with tapered portions 36 and 38 at each end thereof. Stent 20 is released from

sleeves 22 and 24 upon expansion of balloon 14 by pulling out of the sleeves and the bunching back of the sleeves. As seen in Figure 2 the stent deploys. The sleeves contract about balloon 14 when it is deflated. Deflation allows balloon 14 and sleeves 22 and 24 along with catheter 10 to be axially removed from the body.

In situations where the stent OD is large relative to the stretched ID of the sleeves; such as .060 inches as compared to .032-.038, the fit between the sleeve ID and the balloon end portion tends to be so large as to create difficulty in forming an acceptable profile for the catheter and it is difficult to sufficiently increase the OD of the balloon catheter to provide adequate interference fit of the stent to the balloon. The rings provide increased friction fit in such instances and aid in controlling spring-back of the crimped stent.

In assembling the polyurethane sleeves, they can be temporarily swelled by exposure to a solvent such as toluene, alcohol, or others as known in the art, then pushed on the ends of the stent. The sleeves are then bonded to the balloon ends with a polyurethane adhesive or the like.

Other embodiments are within the claims to this invention. For example, referring to Figure 3, the rings 34 seen in Figures 1 and 2 may take the form of wire coils 34a which may for example be stainless steel or Nitinol or polyamides such as nylon.

Referring to Figure 4, the sleeves 22 and 24 of the preceding Figures may take the form of spiral coils of plastic 22a and 24a such as polyamide or polyethylene or polyimide for example. The spiral may be cut only partially into the body as a spiral cut or it may be cut all the way through as shown.

Referring to Figures 5 and 6, the sleeves 22 and 24 of the preceding Figures may be replaced by metal such as stainless steel or Nitinol coils 22b (not shown) and 24b, for example. Figure 5 shows such coils engaging stent 20 in the loaded or crimped position, ready for delivery. Figure 6 shows the coils retracted by balloon expansion with stent 20 partially expanded and ready to be deployed.

Referring to Figures 7 and 8, metal coils 22b (not shown) and 24b of Figures 5 and 6 may take the form of flat coiled ribbons 22c and 24c in either metal or plastic of the types already described. In Figure 7 the coiled ribbons 22c and 24c are shown engaging the stent 20 in the loaded or crimped position, ready for delivery.

Figure 8 shows them retracted by balloon expansion with stent 20 partially expanded ready for deployment.

Any body compatible metal and plastic having the requisite strength characteristics, and/or other physical characteristics may be used in the various embodiments of this invention.

Alternative embodiments are shown in Figures 9-13. These embodiments are basically the same as those mentioned above, except for the positioning of the ring. Combinations of the embodiments may be employed. Referring to Figures 9 and 10, a stent delivery system 110 includes a catheter such as an over-the-wire or rapid exchange. Shown is a catheter 110 having a outer shaft 116, a guidewire lumen 118 with marker band secured thereto 115 and a distal tip 117. As above, balloon 114 is fixed to the distal end of the catheter by adhesive attachment of the proximal end to the outer shaft 116 of the catheter and the distal end to the inner shaft 118 of the catheter. Other arrangements known in the art may be used. Balloon 114 is shown in Figure 9 in its contracted state and in Figure 10 in its expanded state. A stent 120 is fixed about balloon 114 by two overlying retaining sleeves, or socks, 122 and 124, which cover the ends 130, 132 of the stent, respectively.

Various types of stents may be used with balloon expansion, as described above.

Stent 120 is radially compressed, as by crimping to a contracted condition, against balloon 114 to a relatively small loaded diameter having an OD of .044 inches for example, although it has a larger released diameter in the expanded condition.

As above, sleeves 122 and 124 may be formed of polyurethane tubing or the like, having for example an ID of .032-.038 inches and a wall thickness of .002-.004 inches, for example, and are axially fixed along catheter 110 to the proximal end of balloon 114 at 126 and to the distal end of balloon 114 at 127 by means of polyurethane adhesive 126, 127.

As above, the sleeves may be of an expandable material, preferable elastomers such as polyurethane, silicone, latex or polyether amide, by way of example only, most preferably polyurethane or polyolefin copolymer (POC); Surlyn™. The

material should be formable into a thin walled tube. Only one sleeve may be provided at one end of the stent, preferably the proximal end. However, the use of a pair of sleeves, one at each end of the stent, is most preferred.

Sleeves 122 and 124 overlap stent 120 at each of its ends 130 and 132, respectively. For example, the overlap may be .5-1.5 mm. Rings 134 are included under, and preferably adhered to, the sleeves 122 and 124 positioned on the cone portion of the balloon 114, preferably the upper portion, when the balloon is in its collapsed configuration. The rings may be attached to the sleeves with adhesive such as a polyurethane adhesive. The rings may be rigid or any material which effectively retains its substantially annular shape, preferably non-elastomeric material, including plastic, such as polyimide or polyethylene, or metal, such as platinum, gold, stainless steel or Nitinol, and may be .25-.5 mm in length and the ID of the ring is to match the desired OD of the upper portion of the cone portion. In the alternative, the sleeve material may be of a higher Durometer urethane or even merely may have a thicker annular region in the sleeve to function as a ring. The function of the rings is to more effectively and smoothly draw the sleeve off of the ends of the stent, by creating a more axial force on the ring 134.

Referring to Figure 10, in its expanded state balloon 114 has an enlarged diameter with tapered cone portions 136 and 138 at each end thereof. Stent 120 is released from sleeves 122 and 124 upon expansion of balloon 114 due to the axial force created by the ring which draws the sleeves gradually outward, bunching the sleeve between the rings 134 and the fixed position of the sleeve on the catheter. As the balloon is inflated, a combination of radial and axial forces are applied to the ring 134. Since the rings resist the radial force, they are driven primarily axially, dragging the sleeve off of the ends of the stent and balloon. The increased axial pressure allows for a more controlled and steady release of the stent and balloon, as opposed to a sudden release which may happen when the primary force on the ring is in the radial direction. As seen in Figure 10 the stent deploys. The sleeves contract about balloon 114 when it is deflated. Deflation allows balloon 114 and sleeves 122 and 124 along with catheter 110 to be axially removed from the body.

The positioning of the rings 134, which provides for greater axial force, allow the sleeves to be made of softer and thinner material, such as softer grades of urethanes, which include the use of lower Durometer urethane such as 65-95A or 55D (55D Durometer urethane), for example Tecothane 1055D. This is an advantage because the ring is the active movement mechanism pulling the sleeve off the balloon, releasing the stent, and by improving the flexibility of the sleeves improves the overall flexibility of the catheter, thus improving the tracking of the system through the coronary vascular. It is desirous to have the sleeve smoothly slide down the cone of the balloon without appreciably expanding.

In assembling the polyurethane sleeves, they can be temporarily swelled by exposure to a solvent such as toluene, alcohol, or others as known in the art, then pushed on the ends of the stent. The sleeves are then bonded to the balloon ends with a polyurethane adhesive or the like. The rings are either held in place by the tension between the sleeves and balloon or the rings are attached to the sleeves.

Other embodiments are within the claims to this invention. For example, referring to Figure 11, the rings 134a seen in Figures 9 and 10 may take the form of wire coils 134a which may for example be stainless steel or Nitinol or polyamides such as nylon.

Referring to Figure 12, the sleeves 122 and 124 of the preceding Figures may take the form of spiral coils of plastic 122a and 124a such as polyamide or polyethylene or polyimide for example. The spiral may be cut only partially into the body as a spiral cut or it may be cut all the way through as shown.

The rings 134 are preferably circular in shape, but may also be any regular polygon. Figure 13a-c illustrate possible designs of the rings 134. The ring of Figure 13a has a tapered profile to conform to the cones' tapered profiles. Figure 13b illustrates a typical tubular ring and Figure 13c illustrates a coil ring.

Any body compatible metal and plastic having the requisite strength characteristics, and/or other physical characteristics may be used in the various embodiments of this invention.

The above examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and

alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the attached hereto.

CLAIMS

What is claimed is:

1. A stent delivery system comprising:

a catheter comprising an expandable distal portion constructed and arranged for expanding the outer diameter of said catheter from a contracted state to an expanded state;

a stent positioned around said distal portion of said catheter, said stent having a contracted condition and being expandable to an expanded condition, and being sized in said contracted condition to closely surround said catheter in the contracted state, said stent having at least an end portion lying over said expandable portion of said catheter;

a sleeve in the region of said distal portion of said catheter and positioned around said catheter, having a first end fixed to said catheter, and a second end lying over said end portion of said stent; and

at least one ring positioned between the sleeve and the expandable distal portion of the catheter,

said sleeve retaining said end of said stent on said catheter when said catheter is in the contracted state, said catheter and stent cooperatively constructed and arranged for expansion of said catheter from said contracted state to said expanded state and to cause said sleeve and ring to slide relatively axially, drawing said sleeve from over said stent, thereby releasing said end of the stent from said catheter.

2. The stent delivery system of claim 1, wherein said at least one ring is attached to said second end of said sleeve and positioned around said stent end and wherein said expansible distal portion comprises a balloon mounted on a shaft of the catheter, whereby said stent is expanded by expansion of said balloon.

3. The stent delivery system of claim 2, said sleeve being formed from polyurethane.

4. The stent delivery system of claim 2, said sleeve being formed from any elastomer able to be expanded with a balloon angioplasty catheter, and formable into a thin-walled tube in the shape of a cylinder.

5. The stent delivery system of claim 2, said end of said stent being a distal end, wherein said sleeve fixes said stent at the distal end of said stent.

6. The stent delivery system of claim 2, said ring being formed in the shape of a coil.

7. The stent delivery system of claim 6 wherein said coil is plastic.

8. The stent delivery system of claim 6 wherein the coil is metal.

9. The stent delivery system of claim 6 wherein the ring is metal.

10. The stent delivery system of claim 6 wherein the ring is plastic.

11. The stent delivery system of claim 1, said stent having a first and second end portion lying over said expandable portion of said catheter, the delivery system comprising:

a first and second sleeve in the region of said distal portion of said catheter and positioned around said catheter, each having a first end fixed to said catheter, and a second end lying over a said end of said stent; and

a first and second ring, each being respectively attached to said first and second sleeves and positioned around said ends of said stent,

said first sleeve and first ring and said second sleeve and second ring separately engaging said stent at said first end and said second end respectively and said first and second sleeves and rings fixing said ends of said stent on said catheter when said catheter is in the contracted state, said catheter and stent cooperatively constructed or arranged for expansion of said catheter from said contracted state to said expanded state to cause expansion of said stent, including said first and second ends of said stent, from said contracted condition to said expanded condition, and thereby causing said sleeves and rings to slide relatively axially from over the margins of said stent, thereby simultaneously releasing said ends of the stent from said catheter.

12. The stent delivery system of claim 11 wherein said expansible distal portion comprises a balloon mounted on a shaft of the catheter, whereby said stent is expanded by expansion of said balloon.

13. The stent delivery system of claim 11, said sleeve being formed from polyurethane.

14. The stent delivery system of claim 11, said sleeve being formed from any elastomer able to be expanded with a balloon angioplasty catheter, and formable into a thin-walled tube in the shape of a cylinder.

15. The stent delivery system of claim 11, said end of said stent being a distal end, wherein said sleeve fixes said stent at the distal end of said stent.

16. The stent delivery system of claim 11, said ring being formed in the shape of a coil formed of plastic or metal.

17. The stent delivery system of claim 11 wherein the ring is metal or plastic.

18. A stent delivery system comprising:

a catheter comprising an expansible distal portion constructed and arranged for expanding the outer diameter of said catheter from a contracted state to an expanded state;

a stent positioned around said distal portion of said catheter, said stent having a contracted condition and being expansible to an expanded condition, and being sized in said contracted condition to closely surround said catheter in the contracted state, said stent having at least an end portion defining a margin lying over said expandable portion of said catheter;

a coil in the region of said distal portion of said catheter and positioned around said catheter, having a first end fixed to said catheter, and a second end defining a margin lying over said end portion of said stent;

said coil fixing said end of said stent on said catheter when said catheter is in the contracted state, said catheter and stent cooperatively constructed and arranged to cause expansion of said catheter from said contracted state to said expanded state and to cause expansion of said stent, including said end of said stent, from said contracted condition to said expanded condition, thereby causing said sleeve to slide relatively axially from over the margin of said stent, thereby releasing said end of the stent from said catheter.

19. The stent delivery system of claim 18 wherein the coil includes a ring attached to said end overlying said stent.

20. The stent delivery system of claim 18 wherein said coil is plastic or metal.

21. The stent delivery system of claim 18 wherein said coil is rounded in cross-section.

22. The stent delivery system of claim 18 wherein said coil is ribbon-like in cross-section.

23. The stent delivery system of claim 18, wherein said expansible distal portion comprises a balloon mounted on a shaft of the catheter.

24. The stent delivery system of claim 23, wherein said stent is expanded by expansion of said balloon.

25. The stent delivery system of claims 18 or 24, said stent having first and second end portions, each end portion defining a margin lying over said expandable portion of said catheter, the delivery system comprising, a first and second coil in the region of said distal portion of said catheter positioned around said catheter, each having a first end fixed to said catheter and a second end defining a margin lying over said ends of said stent, said first coil and said second coil separately engaging said stent at said first end and said second end respectively, said coil fixing said ends of said stent on said catheter when said catheter is in the contracted state, said catheter and stent cooperatively constructed and arranged for expansion of said catheter from said contracted state to said expanded state to cause said coils to slide relatively axially from over the margins of said stent, thereby simultaneously releasing said ends of the stent from said catheter.

26. The stent delivery system of claim 1 wherein said expansible distal portion comprises a balloon, whereby said stent is expanded by expansion of said balloon, having at least one cone portion mounted on a shaft of the catheter and wherein the ring is positioned between the cone portion and the sleeve when the balloon is in its contracted state.

27. The stent delivery system of claim 26, said sleeve being formed from polyurethane.

28. The stent delivery system of claim 26, said sleeve being formed from any elastomer able to be expanded with a balloon angioplasty catheter, and formable into a thin-walled tube in the shape of a cylinder.

29. The stent delivery system of claim 26, said end of said stent being a proximal end, wherein said sleeve covers said stent at the proximal end of said stent.

30. The stent delivery system of claim 26, said ring being formed in the shape of a coil formed of plastic or metal.

31. The stent delivery system of claim 30 wherein said coil is plastic or metal.

32. The stent delivery system of claim 26 wherein the ring is metal or plastic.

33. The stent delivery system of claim 1, said stent having a first and second end portion lying over said expandable portion of said catheter, the delivery system comprising:

a first and second sleeve in the region of said distal portion of said catheter and positioned around said catheter, each having a first end fixed to said catheter, and a second end lying over a said end portion of said stent; and

a first and second ring, each being respectively attached to said first and second sleeves and positioned between said sleeves and said expandable portion of said catheter, wherein said expansible distal portion comprises a balloon having cone portions mounted on a shaft of the catheter and wherein the rings are positioned between the cone portions and the respective sleeves when the balloon is in its contracted state, said first sleeve and said second sleeve separately engaging said stent at said first end and said second end respectively, said first and second sleeves covering said ends of said stent on said catheter when said catheter is in the contracted state, and said rings being adhered to said sleeves between said sleeves and said expandable portion of the catheter distal and proximal to said distal and proximal ends of said stent, respectively, said catheter and stent cooperatively constructed or arranged for expansion of said catheter from said contracted state to said expanded state to cause expansion of said stent, including said first and second ends of said stent, from said contracted condition to said expanded condition, and thereby causing said rings to slide relatively axially, drawing said sleeve from over said stent, thereby releasing said end of the stent from said catheter.

34. The stent delivery system of claim 33, said sleeve being formed from polyurethane.

35. The stent delivery system of claim 33, said sleeve being formed from any elastomer able to be expanded with a balloon angioplasty catheter, and formable into a thin-walled tube in the shape of a cylinder.

36. The stent delivery system of claim 33, said ring being formed in the shape of a coil of plastic or metal.

37. The stent delivery system of claim 33 wherein the ring is metal or plastic.

38. A stent delivery system comprising:

a catheter comprising an expandable distal portion constructed and arranged for expanding the outer diameter of said catheter from a contracted state to an expanded state;

a stent positioned around said distal portion of said catheter, said stent having a contracted condition and being expandable to an expanded condition, and being sized in said contracted condition to closely surround said catheter in the contracted state, said stent having at least an end portion lying over said expandable portion of said catheter; and

a sleeve in the region of said distal portion of said catheter and positioned around said catheter, having a first end fixed to said catheter, and a second end lying over said end portion of said stent, the sleeve having a substantially rigid annular portion integral with the sleeve material, said sleeve retaining said end of said stent on said catheter when said catheter is in the contracted state, said catheter and stent cooperatively constructed and arranged for expansion of said catheter from said contracted state to said expanded state and to cause said sleeve and rigid annular portion to slide relatively axially, drawing said sleeve from over said stent, thereby releasing said end of the stent from said catheter.

Fig. 1

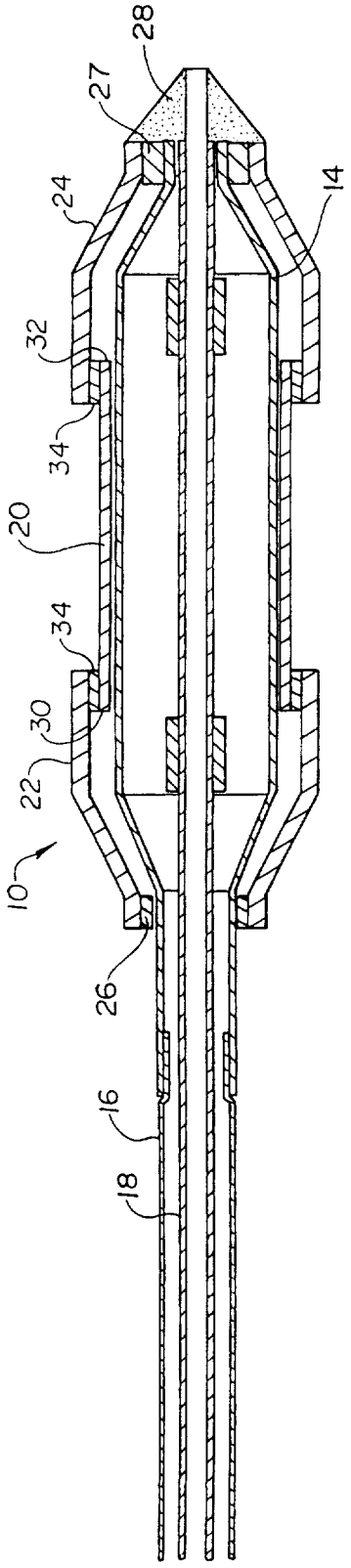
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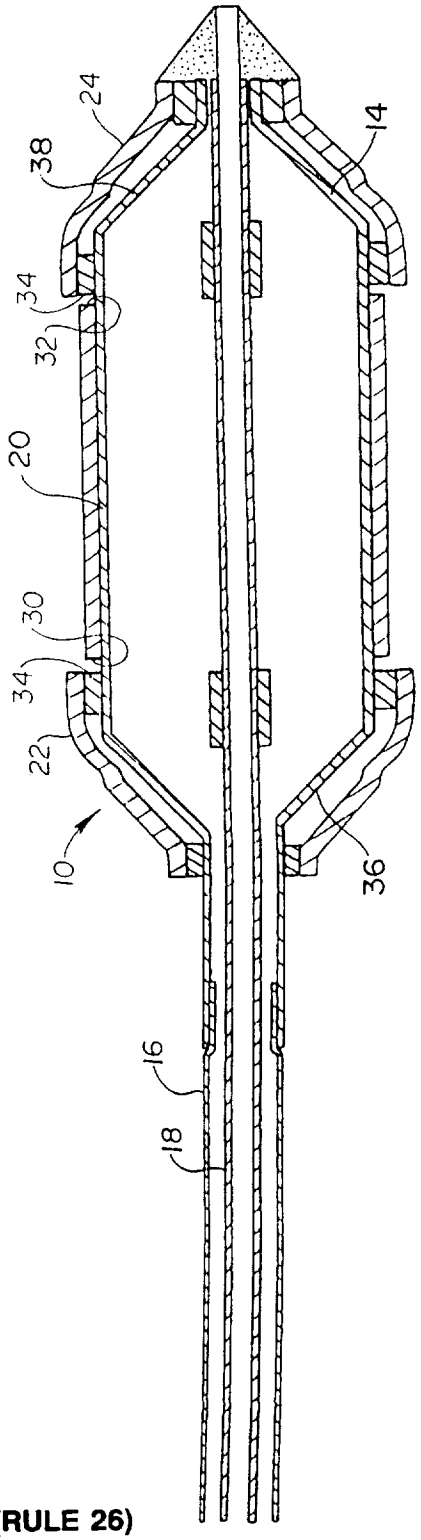
Fig. 2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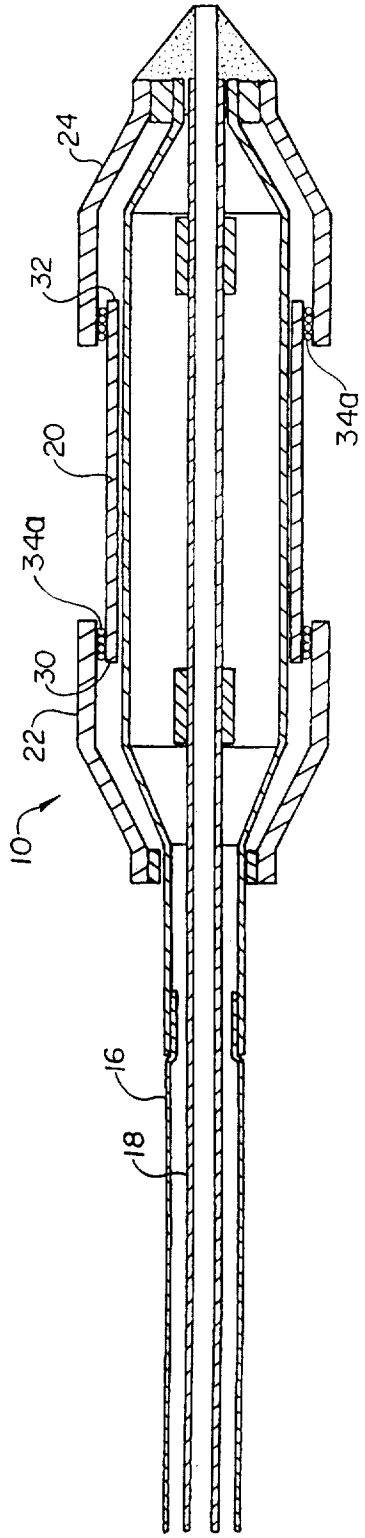


Fig. 3

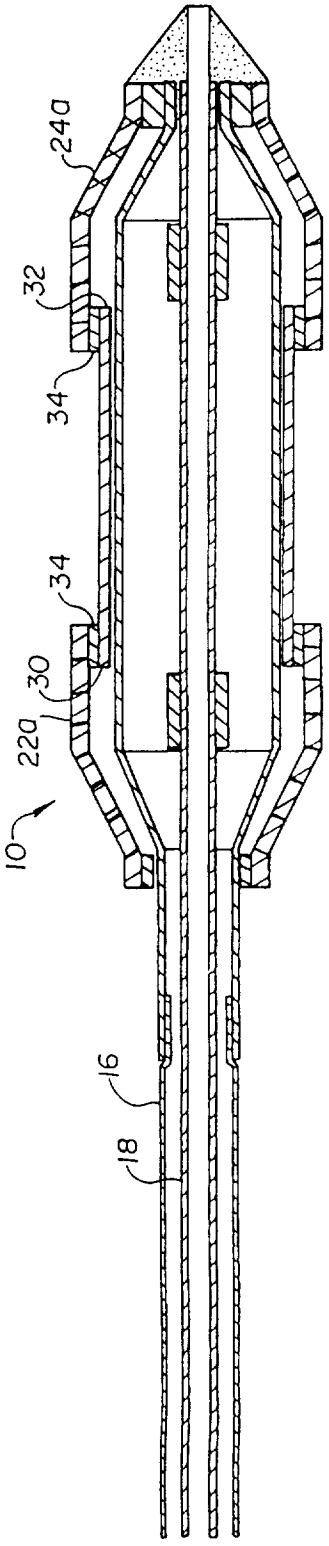


Fig. 4

Fig. 5

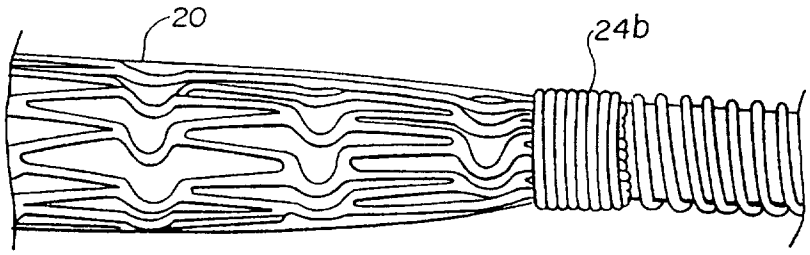


Fig. 6

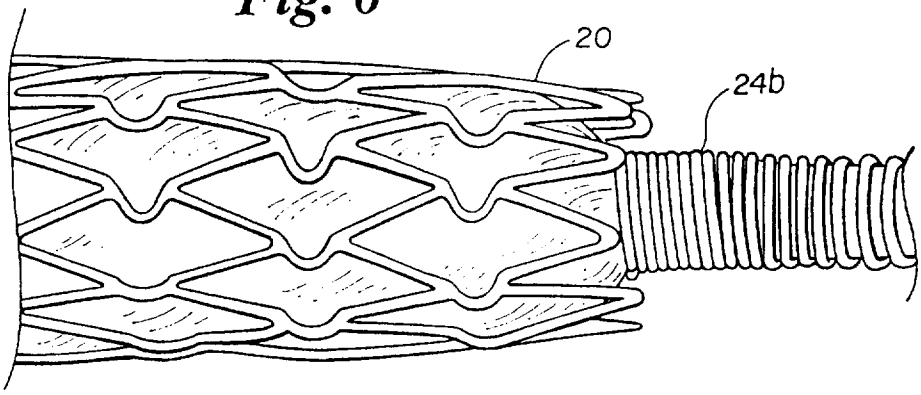


Fig. 7

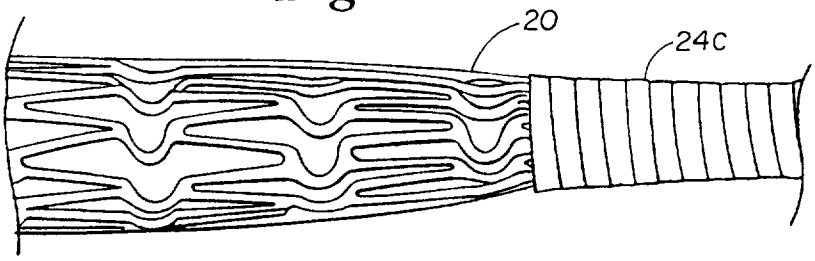
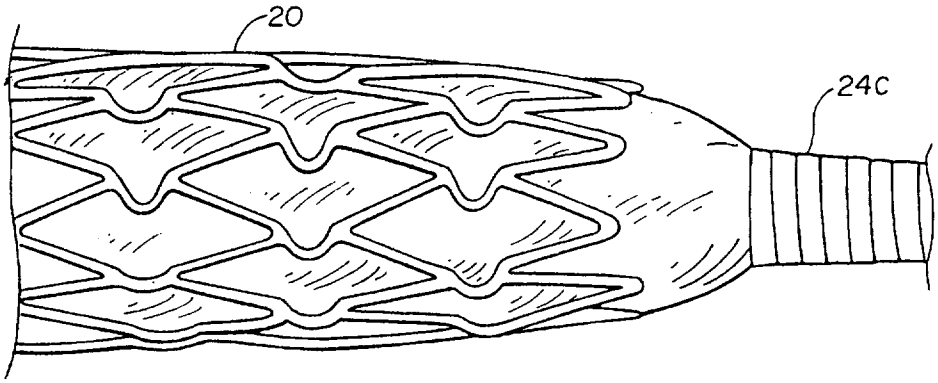


Fig. 8



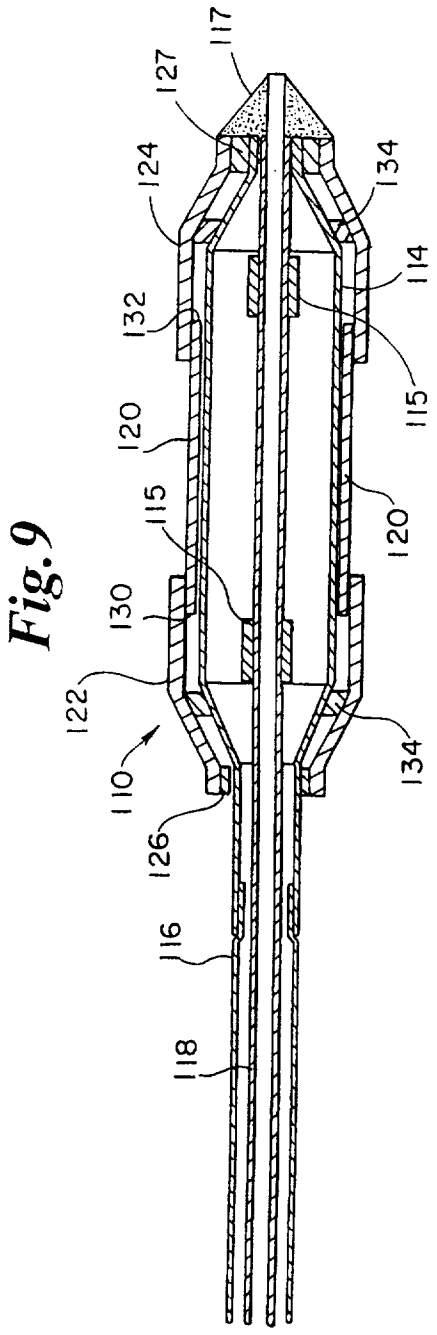

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Fig. 9

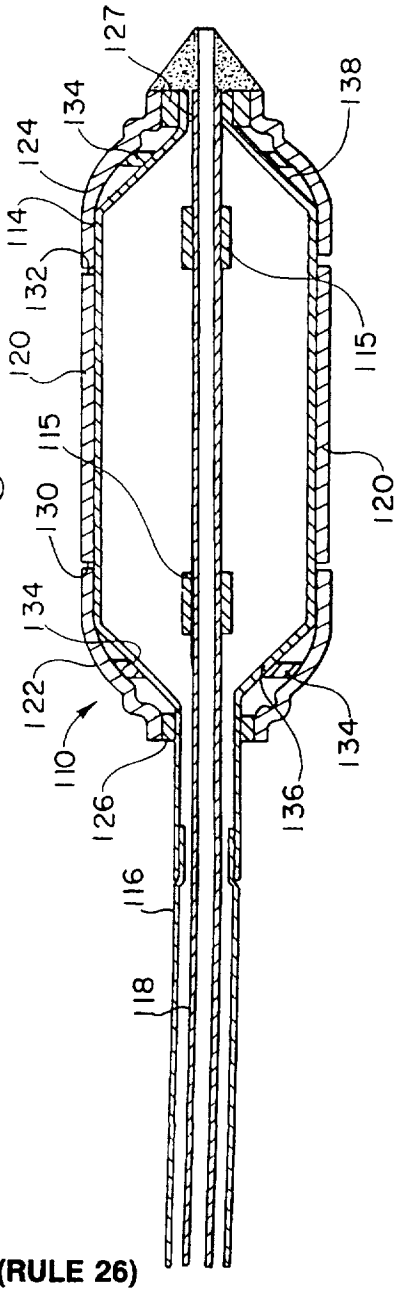
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Fig. 10

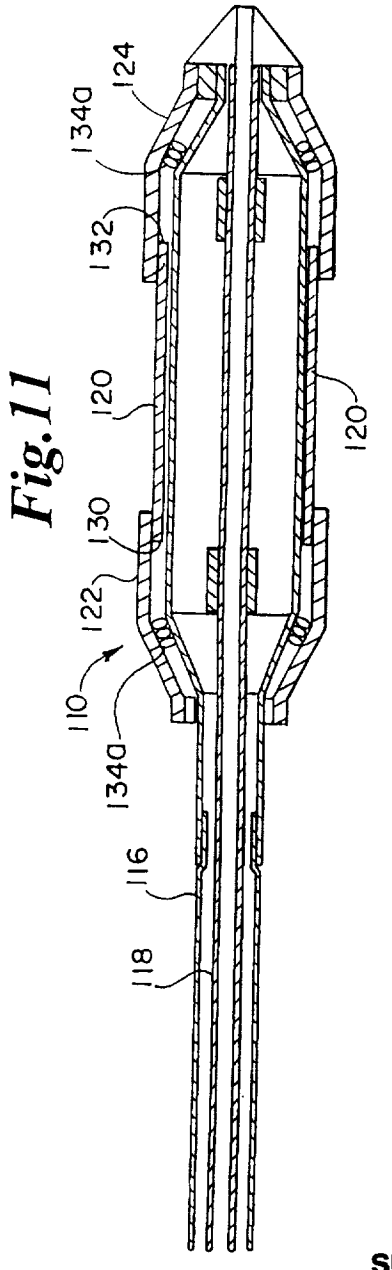

Fig.11

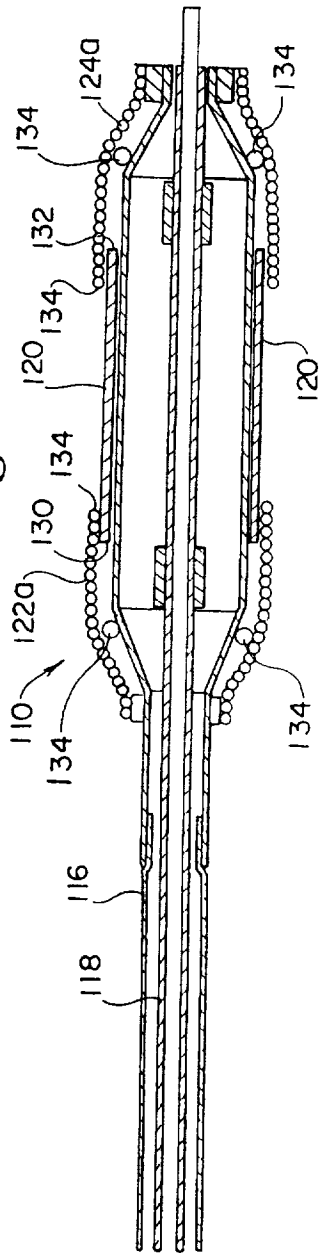

Fig.12

Fig. 13c

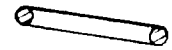

Fig. 13b

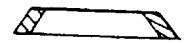

Fig. 13a

INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/US 97/14141

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP 0 442 657 A (C.R. BARD) 21 August 1991 see column 7, line 24 - column 8, line 9 see column 8, line 54 - column 9, line 23; figures 7A-C,9A-B	38 1,11
P,X	US 5 643 278 A (WIJAY) 1 July 1997 see column 4, line 35 - line 45; figures	18,20, 23,24
A	WO 90 05554 A (BOSTON SCIENTIFIC) 31 May 1990 see abstract; figures	1,11

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

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 December 1997	15/12/1997

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hagberg, A

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INTERNATIONAL SEARCH REPORT

Inte ional Application No
PCT/US 97/14141

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 442657 A	21-08-91	US 5108416 A	28-04-92
		AU 7097791 A	15-08-91
		JP 7051382 A	28-02-95
US 5643278 A	01-07-97	NONE	
WO 9005554 A	31-05-90	US 4950227 A	21-08-90
		DE 68927998 D	28-05-97
		DE 68927998 T	11-09-97
		EP 0409929 A	30-01-91
		JP 6503481 T	21-04-94