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(54) METHOD FOR MOUNTING BLADES TO A CUTTING BALLOON CATHETER

VERFAHREN ZUR BEFESTIGUNG VON KLINGEN AN EINEM SCHNEIDENDEN BALLONKATHETER

PROCÉDÉ DE MONTAGE DE LAMES SUR UN CATHÉTER BALLON COUPANT

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Description

Field of the Invention

[0001] The present invention pertains to balloon catheters and methods for making balloon catheters. More particularly, the present invention pertains to angioplasty balloon catheters that include one or more cutting blades coupled to the angioplasty balloon and methods for making cutting balloon catheters.

Background

[0002] Heart and vascular disease are major problems in the United States and throughout the world. Conditions such as atherosclerosis result in blood vessels becoming blocked or narrowed. This blockage can result in lack of oxygenation of the heart, which has significant consequences because the heart muscle must be well oxygenated in order to maintain its blood pumping action.

[0003] Occluded, stenotic, or narrowed blood vessels may be treated with a number of relatively non-invasive medical procedures including percutaneous transluminal angioplasty (PTA), percutaneous transluminal coronary angioplasty (PTCA), and atherectomy. Angioplasty techniques typically involve the use of a balloon catheter. The balloon catheter is advanced over a guidewire so that the balloon is positioned adjacent a stenotic lesion. The balloon is then inflated, and the restriction of the vessel is opened.

[0004] One of the major obstacles in treating coronary artery disease and/or treating blocked blood vessels is re-stenosis. Evidence has shown that cutting the stenosis, for example, with an angioplasty balloon equipped with a cutting blade during treatment can reduce incidence of re-stenosis. Additionally, cutting the stenosis may reduce trauma at the treatment site and/or may reduce the trauma to adjacent healthy tissue. Cutting blades may also be beneficial additions to angioplasty procedures when the targeted occlusion is hardened or calcified. It is believed typical angioplasty balloons, alone, may not be able to expand certain of these hardened lesions. Thus, angioplasty balloons equipped with cutting edges have been developed to attempt to enhance angioplasty treatments. There is an ongoing need for improved angioplasty devices, including cutting angioplasty balloons, and improved methods of treating intravascular stenoses and occlusions. In addition, there is an ongoing need for new methods for making cutting balloon catheters. US-A-5 320 634 discloses a balloon catheter whereby metallic cutting members are submerged in substrates that are attached to the outer surface of the balloon.

Brief Summary

[0005] The present invention relates to a method for manufacturing angioplasty balloon catheters as claimed in claim 1, with preferred embodiments in the dependent claims. One or more cutting members or blades are coupled to the balloon. These methods include providing a joining member, attaching a cutting blade to the joining member, and attaching the joining member to a balloon. These and other features are described in more detail below.

Brief Description of the Drawings

[0006]

Figure 1 is a partial cross-sectional side view of an example cutting balloon catheter disposed in a blood vessel;

Figure 2 is a partial perspective view of an example cutting member and a joining member for connecting the cutting member to a balloon;

Figure 3 is a side view of a cutting member and a joining member corresponding to the invention; and

Figure 4 is a side view of a cutting member, a joining member, and a portion of a balloon.

Detailed Description

[0007] The following description should be read with reference to the drawings wherein like reference numerals indicate like elements throughout the several views. The detailed description and drawings illustrate example embodiments of the claimed invention.

[0008] Figure 1 is a partial cross-sectional side view of an example catheter 10 disposed in a blood vessel 12 and positioned adjacent an intravascular lesion 14. Catheter 10 may include a balloon 16 coupled to a catheter shaft 18. One or more cutting members or blades 20 may be coupled to balloon 16. In general, catheter 10 may be advanced over a guidewire 22, through the vasculature, to a target area. Balloon 16 can then be inflated to expand lesion 14, and cutting members 20 may cut lesion 14. The target area may be within any suitable peripheral or cardiac vessel lumen location.

[0009] The invention relates to methods for making catheters, for example, like catheter 10. Some of the methods for making catheters disclosed herein relate to the way cutting members 20 are attached to balloon 16. Attaching cutting members 20 to balloon 16 may be accomplished in a number of ways. For example, a joining member 38 (not shown in Figure 1, best seen in Figure 2) may be disposed between cutting members 20 and balloon 16. The method for attaching cutting member 20 may include attaching cutting member 20 to joining member 38 and attaching joining member 38 to balloon 16. In some embodiments, cutting member 20 may be attached to joining member 38 prior to attaching joining member 38 to balloon 16. In other embodiments, the order may be reversed. A more detailed description of some of the methods for coupling cutting members 20 with balloon 16 is provided below.

[0010] Cutting members 20 may made from any suitable material such as a metal, metal alloy, metal-polymer composite, and the like. For example, cutting member 20 may be made from stainless steel such as 304V, 304L, or 316L stainless steel. In some other embodiments, cutting member 20 is made from an iron-cobalt-nickel alloy such as Aermet®100, which is commercially available from Carpenter Technology Corporation. Some examples of other suitable materials are listed below in relation to balloon 16 and shaft 18. Cutting members 20 may vary in number, position, and arrangement about balloon 16. For example, catheter 10 may include one, two, three, four, five, six, or more cutting members 20 that are disposed at any position along balloon 16 and in a regular, irregular, or any other suitable pattern.

[0011] Balloon 16 may be made from typical angioplasty balloon materials including polymers such as polyethylene terephthalate (PET), polyetherimid (PEI), polyethylene (PE), etc. Some other examples of suitable polymers, including lubricious polymers, may include polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), fluorinated ethylene propylene (FEP), polyoxymethylene (POM), polybutylene terephthalate (PBT), polyether block ester, polyurethane, polypropylene (PP), polyvinylchloride (PVC), polyether-ester (for example, a polyether-ester elastomer such as ARNITEL® available from DSM Engineering Plastics), polyester (for example, a polyester elastomer such as HYTREL® available from DuPont), polyamide (for example, DURETHAN® available from Bayer or CRISTAMID® available from Elf Atochem), elastomeric polyamides, block polyamide/ethers, polyether block amide (PEBA, for example, available under the trade name PEBAX®), silicones, Marlex high-density polyethylene, Marlex low-density polyethylene, linear low density polyethylene (for example, REXELL®), polyetheretherketone (PEEK), polyimide (PI), polyphenylene sulfide (PPS), polyphenylene oxide (PPO), polysulfone, nylon, perfluoro(propyl vinyl ether) (PFA), other suitable materials, or mixtures, combinations, copolymers thereof, polymer/metal composites, and the like. In some embodiments, it may be desirable to use high modulus or generally stiffer materials so as to reduce balloon elongation. The above list of materials includes some examples of higher modulus materials. Some other examples of stiffer materials include polymers blended with liquid crystal polymer (LCP) as well as the materials listed above. For example, the mixture can contain up to about 5% LCP.

[0012] Balloon 16 may be configured so that it includes one or more "wings" or wing-shaped regions when balloon 16 is deflated. These wings may appear as a plurality of alternating inward and outward radial deflections in balloon 16 when balloon 16 is deflated. These wings may be desirable for a number of reasons. For example, by including balloon 16 with wings, balloon 16 may have more predictable and consistent re-folding characteristics. Additionally, the wings may be configured so that cutting members 20 can be positioned at the inward-most positions of the deflated balloon 16. This arrangement allows cutting members 20 to be positioned more closely to shaft 18 when balloon 16 is deflated. Accordingly, cutting members 20 can be moved away from the vessel walls where they might otherwise result in contact and, possibly, damage to healthy tissue during movement of catheter 10 within a body lumen. Additionally, alternating the wings and cutting members 20 as well as positioning cutting members 20 relatively close to shaft 18 may allow the wings to fold over and cover cutting members 20 when balloon 16 is deflated. Again, this feature may reduce the exposure of cutting members 20 to the blood vessel.

[0013] Shaft 18 may be a catheter shaft, similar to typical catheter shafts. For example, shaft 18 may include an inner tubular member 24 and outer tubular member 26. Tubular members 24/26 may be manufactured from a number of different materials. For example, tubular members 24/26 may be made of metals, metal alloys, polymers, metal-polymer composites or any other suitable materials. Some examples of suitable metals and metal alloys include stainless steel, such as 300 series stainless steel (including 304V, 304L, and 316L); 400 series martensitic stainless steel; tool steel; nickel-titanium alloy such as linear-elastic or super-elastic Nitinol, nickel-chromium alloy, nickel-chromium-iron alloy, cobalt alloy, tungsten or tungsten alloys, MP35-N (having a composition of about 35% Ni, 35% Co, 20% Cr, 9.75% Mo, a maximum 1% Fe, a maximum 1% Ti, a maximum 0.25% C, a maximum 0.15% Mn, and a maximum 0.15% Si), hastelloy, monel 400, inconel 825, or the like; or other suitable material. Some examples of suitable polymers include those described above in relation to balloon 16. Of course, any other polymer or other suitable material including ceramics may be used without departing from the spirit of the invention. The materials used to manufacture inner tubular member 24 may be the same as or be different from the materials used to manufacture outer tubular member 26. Those materials listed herein may also be used for manufacturing other components of catheter 10, including cutting members 20.

[0014] Tubular members 24/26 may be arranged in any appropriate way. For example, in some embodiments inner tubular member 24 can be disposed coaxially within outer tubular member 26. According to these embodiments, inner and outer tubular members 24/26 may or may not be secured to one another along the general longitudinal axis of shaft 18. Alternatively, inner tubular member 24 may follow the inner wall or otherwise be disposed adjacent the inner wall of outer tubular member 26. Again, inner and outer tubular members 24/26 may or may not be secured to one another. For example, inner and outer tubular members 24/26 may be bonded, welded (including tack welding or any other welding technique), or otherwise secured at a bond point. In some embodiments, the bond point may be generally disposed near the distal end of shaft 18. However, one or more bond points may be disposed at any position along shaft

18. The bond may desirably impact, for example, the stability and the ability of tubular members 24/26 to maintain their position relative to one another. In still other embodiments, inner and outer tubular member 24/26 may be adjacent to and substantially parallel to one another so that they are non-overlapping. In these embodiments, shaft 18 may include an outer sheath that is disposed over tubular members 24/26.

[0015] Inner tubular member 24 may include an inner lumen 28. In at least some embodiments, inner lumen 28 is a guidewire lumen. Accordingly, catheter 10 can be advanced over guidewire 22 to the desired location. The guidewire lumen may extend along essentially the entire length of catheter shaft 18 so that catheter 10 resembles traditional "over-the-wire" catheters. Alternatively, the guidewire lumen may extend along only a portion of shaft 18 so that catheter 10 resembles "single-operator-exchange" or "rapid-exchange" catheters. Regardless of which type of catheter is contemplated, catheter 10 may be configured so that balloon 16 is disposed over at least a region of inner lumen 28. In at least some of these embodiments, inner lumen 28 (i.e., the portion of inner lumen 28 that balloon 16 is disposed over) may be substantially coaxial with balloon 16.

[0016] Shaft 18 may also include an inflation lumen 30 that may be used, for example, to transport inflation media to and from balloon 16. The location and position of inflation lumen 30 may vary, depending on the configuration of tubular members 24/26. For example, when outer tubular member 26 is disposed over inner tubular member 24, inflation lumen 30 may be defined within the space between tubular members 24/26. Moreover, depending on the position of inner tubular member 24 within outer tubular member 26, the shape of lumen 30 (i.e., the shape adjacent shaft 18) may vary. For example, if inner tubular member 24 is attached to or disposed adjacent to the inside surface of outer tubular member 26, then inflation lumen 30 may be generally half-moon in shape; whereas, if inner tubular member 24 is generally coaxial with outer tubular member 26, then inflation lumen 30 may be generally ring-shaped or annular in shape. It can be appreciated that if outer tubular member 26 is disposed alongside inner tubular member 24, then lumen 30 may be the lumen of outer tubular member 26 or it may be the space defined between the outer surface of tubular members 24/26 and the outer sheath disposed thereover.

[0017] Balloon 16 may be coupled to catheter shaft 18 in any of a number of suitable ways. For example, balloon 16 may be adhesively or thermally bonded to shaft 18. In some embodiments, a proximal waist 32 of balloon 16 may be bonded to shaft 18, for example, at outer tubular member 26, and a distal waist 34 may be bonded to shaft 18, for example, at inner tubular member 24. The exact bonding positions, however, may vary. It can be appreciated that a section of proximal waist 32 may have sections 36 extending therefrom in order for suitable bonding between balloon 16 and outer tubular member 30.

[0018] In addition to some of the structures described above, shaft 18 may also include a number of other structural elements, including those typically associated with catheter shafts. For example, shaft 18 may include a radiopaque marker coupled thereto that may aid a user in determining the location of catheter 10 within the vasculature. In addition, catheter 10 may include a folding spring (not shown) coupled to balloon 16, for example, adjacent proximal waist 32, which may further help in balloon folding and refolding. A description of a suitable folding spring can be found in U.S. Patent No. 6,425,882.

[0019] An exploded view depicting joining member 38 and how joining member 38 may be disposed between cutting members 20 and balloon 16 is shown in Figure 2. In general, joining member 38 may be take the form of a strip, band, ribbon, or the like. Joining member 38 may be made from any suitable material such as any of the polymers described herein. For example, joining member 38 may be made from thermoplastic material (i.e., a material whose viscosity changes with the induction of heat), a thermoplastic-like material, a thermoset material, combinations thereof, or the like. Some examples of these and other suitable polymers are listed above. In some embodiments, joining member 38 may be formed from a generally flexible or soft material that allows the interface or connection between cutting member 20 and balloon 16 to be secure while also being, in some embodiments, somewhat elastic or pliable. For example, joining member 38 may be manufactured from a low durometer polyurethane or any other suitable material (including any of the polymers and other materials disclosed herein). Accordingly, cutting member 20 may be securely coupled to balloon 16 while still being able to move laterally about eight degrees or less. Additionally, different portions of cutting member 20 may be able to bend or flex, while other portions remain essentially unchanged. In other embodiments, joining member 38 may be formed from a somewhat harder material.

[0020] In at least some embodiments, joining member 38 can be attached to and disposed between cutting member 20 and balloon 16. For example, joining member 38 can be attached to an outer surface 40 of balloon 16 and to a base 50 of the cutting member 20. The attachment of joining member 38 with cutting member 20 and balloon 16 may be achieved in any appropriate manner, such as by adhesive bonding, casting, thermal bonding, mechanically connecting, welding, brazing, and the like, or in any other suitable way. In some embodiments, attaching joining member 38 with balloon 16 may include bringing joining member 38 into a liquefied, partially liquefied, molten, or partially molten state. According to this embodiment, joining member 38 can be brought into contact with balloon 16 (either while in the liquefied state or just prior to being in the liquefied state), and then become attached to balloon 16 by solidifying. For example, joining member 38 can be heated by directing laser energy onto it prior to bringing joining member 38 into contact with balloon 16. According to this embodiment, the material

making up joining member 38 may become molten or partially molten so that it can meld together with balloon 16 upon cooling. Alternatively, joining member 38 and balloon 16 can be brought into contact, and then laser energy can be directed onto joining member 38 so that joining member 38 can liquefy and meld together with balloon 16.

[0021] As stated above, a number of alternative methods may be used for attaching joining member 38 to balloon 16. For example, joining member 38 may be solvated or partially solvated (i.e., by adding an appropriate solvent) so that it is brought into a solvated liquid or liquefied state. Some examples of a suitable solvents may include tetra hydro furan, which is appropriate for solvating joining members 38 made from polyurethane or hexa fluoro iso propanol, which is appropriate for solvating joining members 38 made from nylon. While in the solvated liquid state, joining member 38 can be brought into contact with balloon 16 and the "liquid" joining member 38 can be allowed to solidify. Alternatively, the suitable solvent can be added after joining member 38 and balloon 16 are brought into contact. This attaching process may additionally include completely or partially removing the solvent. In addition, it may be useful to partially or completely re-solvate joining member 38 in order to perform additional method steps such as attaching cutting members 20. After performing these later-described method steps, it may be, again, appropriate to remove the solvent. It should be noted that the attachment means need not be the same for the attachment between cutting member 20 and joining member 38 as the means used to attach balloon 16 and joining member 38.

[0022] The attachment of cutting member 20 with joining member 38 is shown in Figure 3. In at least some embodiments, joining member 38 can be brought into a liquid or partially liquefied state in any of the manners described above or in any other suitable manner. For example, joining member 38 may be heated so that it melts or partially melts with the use of a laser that directs laser energy onto a portion of joining member 38 such as a top surface 42. Alternatively, joining member 38 may be brought into a solvated or partially solvated state in a manner similar to what is described above.

[0023] With joining member 38 in a partially molten or liquefied state, cutting member 20 can be positioned within joining member 38. cutting member 20 is partially submerged or embedded within joining member 38. This may be accomplished by passing cutting member 20 through a top surface 42 of joining member 38 until cutting member 20 is positioned at the desired depth. The desired depth of insertion can vary, but generally is epitomized by base 50 of cutting member 20 being somewhat spaced from a bottom surface 44 of joining member 38.

[0024] One advantage of partially submerging cutting member 20 within joining member 38 is that the structure of cutting member 20 allows for a secure, interlocking relationship to be formed. Cutting member 20 includes a cutting surface 48 and a series of alternating tabs 52 and holes or openings 54 that are disposed along its base 50. Tabs 52 and openings 54 may be formed in any suitable manner such as with a wire electric discharge milling technique or any other suitable methodology. During the attachment process, the liquefied or partially liquefied joining member 38 can flow into openings 54. Upon solidification, the dispersal of joining member 38 around cutting member 20 can interlock the two structures. This may improve the integrity of the bonding between cutting member 20 with joining member 38. Because joining member 38 will also be bonded with balloon 16 (as shown in Figure 4), this interlocking relationship can also improve the overall bonding between cutting member 20 with balloon 16. In some embodiments, this interlocking type of bond may be more secure than bonding the various components with adhesives.

[0025] It can be appreciated that the step of attaching joining member 38 to cutting member 20 can occur either before or after (or essentially simultaneous with) the step of attaching joining member 38 to balloon 16. For example, joining member 38 may be solvated in order to facilitate attachment of cutting member 20 thereto, and then be partially de-solvated. The remaining solvated portion of joining member 38 can be utilized to attach the joining member 38 and cutting member 20 subassembly to balloon 16. Once the subassembly is attached, the remaining solvent can be removed.

[0026] Collectively, the above discussion elucidates a number of methods for manufacturing catheter 10. For example, one step may include attachment of cutting members 20 with joining member 38 in any of the manners described above. Another step may include attachment of joining member 38 with balloon 16 in any of the manner described above. This step may occur either before or after the step of attaching cutting member 20 with joining member 38. These two attachment steps may further include heating (e.g., with the use of a laser), adding and/or removing a solvent, or any other suitable "liquefying" step as described above.

[0027] It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention as claimed. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

Claims

1. A method for manufacturing a cutting balloon catheter, comprising the steps of:

   providing a joining member (38);
   providing a metallic cutting member (20), the cutting member (20) having a cutting surface (48) and a base (50);
   softening the joining member (38);

positioning the cutting member (20) adjacent the joining member (38) so that the base is submerged within the joining member (38);
solidifying the joining member (38) so that the cutting member (20) and the joining member (38) are secured to one another, and
attaching the joining member (38) and the cutting member (20) to an angioplasty balloon (16), wherein the base (50) of the cutting member (20) includes a series of alternating tabs (52) and openings (54) and wherein the step of positioning the cutting member (20) adjacent the joining member (38) so that the base (50) is submerged within the joining member (38) includes submerging the tabs (52) and openings (54) within the joining member (38); and wherein the step of submerging the tabs (52) and
openings (54) within the joining member (38) interlocks the joining member (38) with the cutting member.

2. The method of claim 1, wherein the step of softening the joining member includes heating the joining member.

3. The method of claim 2, wherein heating the joining member includes heating the joining member with a laser.

4. The method of claim 2, wherein heating the joining member includes melting the joining member.

5. The method of claim 2, wherein heating the joining member includes liquefying the joining member.

6. The method of claim 1, wherein the step of softening the joining member includes at least partially solvating the joining member with a solvent.

7. The method of claim 1, wherein the step of attaching the joining member and the cutting member to an angioplasty balloon includes heating the joining member.

8. The method of claim 7, wherein heating includes heating the joining member with a laser.

9. The method of claim 1, wherein the step of attaching the joining member and the cutting member to an angioplasty balloon includes at least partially solvating the joining member with a solvent.

10. The method of claim 1, further comprising the step of disposing a second cutting member adjacent the joining member.

11. The method of claim 1, wherein the joining member includes a strip of polymeric material.

Patentansprüche

1. Verfahren zum Herstellen eines schneidenden Ballonkatheters mit den Schritten:

Bereitstellen eines Verbindungsteils (38);
Bereitstellen eines metallischen Schneidteils (20), wobei das Schneidteil (20) eine Schneidfläche (48) und eine Basis (50) hat;
Erweichen des Verbindungsteils (38);
Positionieren des Schneidteils (20) benachbart zum Verbindungsteil (38), so dass die Basis im Verbindungsteil (38) versenkt ist;
Verfestigen des Verbindungsteils (38), so dass das Schneidteil (20) und das Verbindungsteil (38) aneinander befestigt sind; und
Anbringen des Verbindungsteils (38) und des Schneidteils (20) an einem Angioplastieballon (16), wobei die Basis (50) des Schneidteils (20) eine Folge abwechselnder Laschen (52) und Öffnungen (54) aufweist und wobei der Schritt des Positionierens des Schneidteils (20) benachbart zum Verbindungsteil (38), so dass die Basis (50) im Verbindungsteil (38) versenkt ist, aufweist: Versenken der Laschen (52) und Öffnungen (54) im Verbindungsteil (38); und wobei der Schritt des Versenkens der Laschen (52) und Öffnungen (54) im Verbindungsteil (38) das Verbindungsteil (38) mit dem Schneidteil verriegelt.

2. Verfahren nach Anspruch 1, wobei der Schritt des Erweichens des Verbindungsteils Erwärmen des Verbindungsteils aufweist.

3. Verfahren nach Anspruch 2, wobei das Erwärmen des Verbindungsteils Erwärmen des Verbindungsteils mit einem Laser aufweist.

4. Verfahren nach Anspruch 2, wobei das Erwärmen des Verbindungsteils Schmelzen des Verbindungsteils aufweist.

5. Verfahren nach Anspruch 2, wobei das Erwärmen des Verbindungsteils Verflüssigen des Verbindungsteils aufweist.

6. Verfahren nach Anspruch 1, wobei der Schritt des Erweichens des Verbindungsteils mindestens teilweises Solvatieren des Verbindungsteils mit einem Lösungsmittel aufweist.

7. Verfahren nach Anspruch 1, wobei der Schritt des Anbringens des Verbindungsteils und des Schneidteils an einem Angioplastieballon Erwärmen des Verbindungsteils aufweist.

8. Verfahren nach Anspruch 7, wobei das Erwärmen

des Verbindungsteils Erwärmen des Verbindungsteils mit einem Laser aufweist.

9. Verfahren nach Anspruch 1, wobei der Schritt des Anbringens des Verbindungsteils und des Schneidteils an einem Angioplastieballon mindestens teilweises Solvatieren des Verbindungsteils mit einem Lösungsmittel aufweist.

10. Verfahren nach Anspruch 1, ferner mit dem Schritt des Anordnens eines zweiten Schneidteils benachbart zum Verbindungsteil.

11. Verfahren nach Anspruch 1, wobei das Verbindungsteil einen Streifen aus Polymermaterial aufweist.

Revendications

1. Procédé de fabrication d'un cathéter à ballon coupant, comprenant les étapes de :

préparation d'un élément d'assemblage (38) ;
préparation d'un élément coupant métallique (20), ledit élément coupant (20) présentant une surface de coupe (48) et une base (50) ;
amollissement de l'élément d'assemblage (38) ;
positionnement de l'élément coupant (20) de façon adjacente à l'élément d'assemblage (38), de manière à noyer la base dans l'élément d'assemblage (38) ;
durcissement de l'élément d'assemblage (38) de manière à fixer l'un à l'autre l'élément coupant (20) et l'élément d'assemblage (38) ; et
fixation de l'élément d'assemblage (38) et de l'élément coupant (20) sur un ballon d'angioplastie (16) ;
où la base (50) de l'élément coupant (20) comprend une série de pattes (52) et d'échancrures (54) alternées, et où l'étape de positionnement de l'élément coupant (20) de façon adjacente à l'élément d'assemblage (38) de manière à noyer la base (50) dans l'élément d'assemblage (38) comprend le noyage des pattes (52) et des échancrures (54) dans l'élément d'assemblage (38) ; et
où l'étape de noyage des pattes (52) et des échancrures (54) dans l'élément d'assemblage (38) emboîte l'élément d'assemblage (38) et l'élément coupant.

2. Procédé selon la revendication 1, où l'étape d'amollissement de l'élément d'assemblage comprend le chauffage de l'élément d'assemblage.

3. Procédé selon la revendication 2, où le chauffage de l'élément d'assemblage comprend le chauffage de l'élément d'assemblage avec un laser.

4. Procédé selon la revendication 2, où le chauffage de l'élément d'assemblage comprend la fonte de l'élément d'assemblage.

5. Procédé selon la revendication 2, où le chauffage de l'élément d'assemblage comprend la liquéfaction de l'élément d'assemblage.

6. Procédé selon la revendication 1, où l'étape d'amollissement de l'élément d'assemblage comprend au moins la dissolution partielle de l'élément d'assemblage au moyen d'un solvant.

7. Procédé selon la revendication 1, où l'étape de fixation de l'élément d'assemblage et de l'élément coupant sur un ballon d'angioplastie comprend le chauffage de l'élément d'assemblage.

8. Procédé selon la revendication 7, où le chauffage comprend le chauffage de l'élément d'assemblage avec un laser.

9. Procédé selon la revendication 1, où l'étape de fixation de l'élément d'assemblage et de l'élément coupant sur un ballon d'angioplastie comprend au moins la dissolution partielle de l'élément d'assemblage au moyen d'un solvant.

10. Procédé selon la revendication 1, comprenant en outre l'étape de positionnement d'un second élément coupant de façon adjacente à l'élément d'assemblage.

11. Procédé selon la revendication 1, où l'élément d'assemblage comprend une bande en matériau polymère.

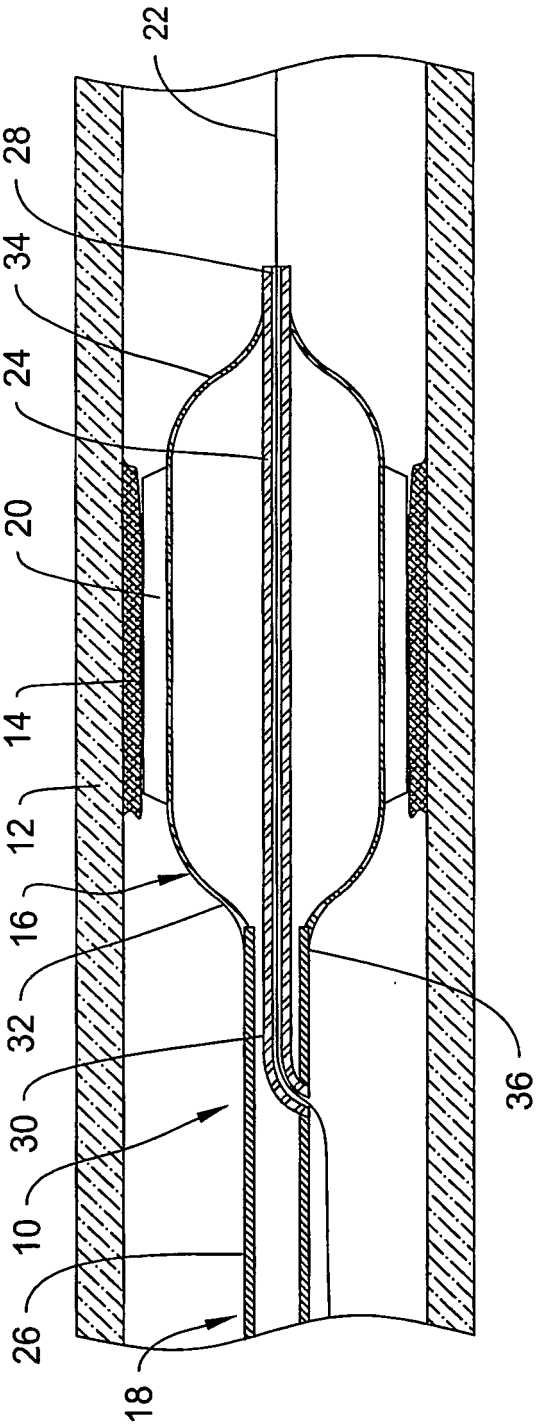

Figure 1

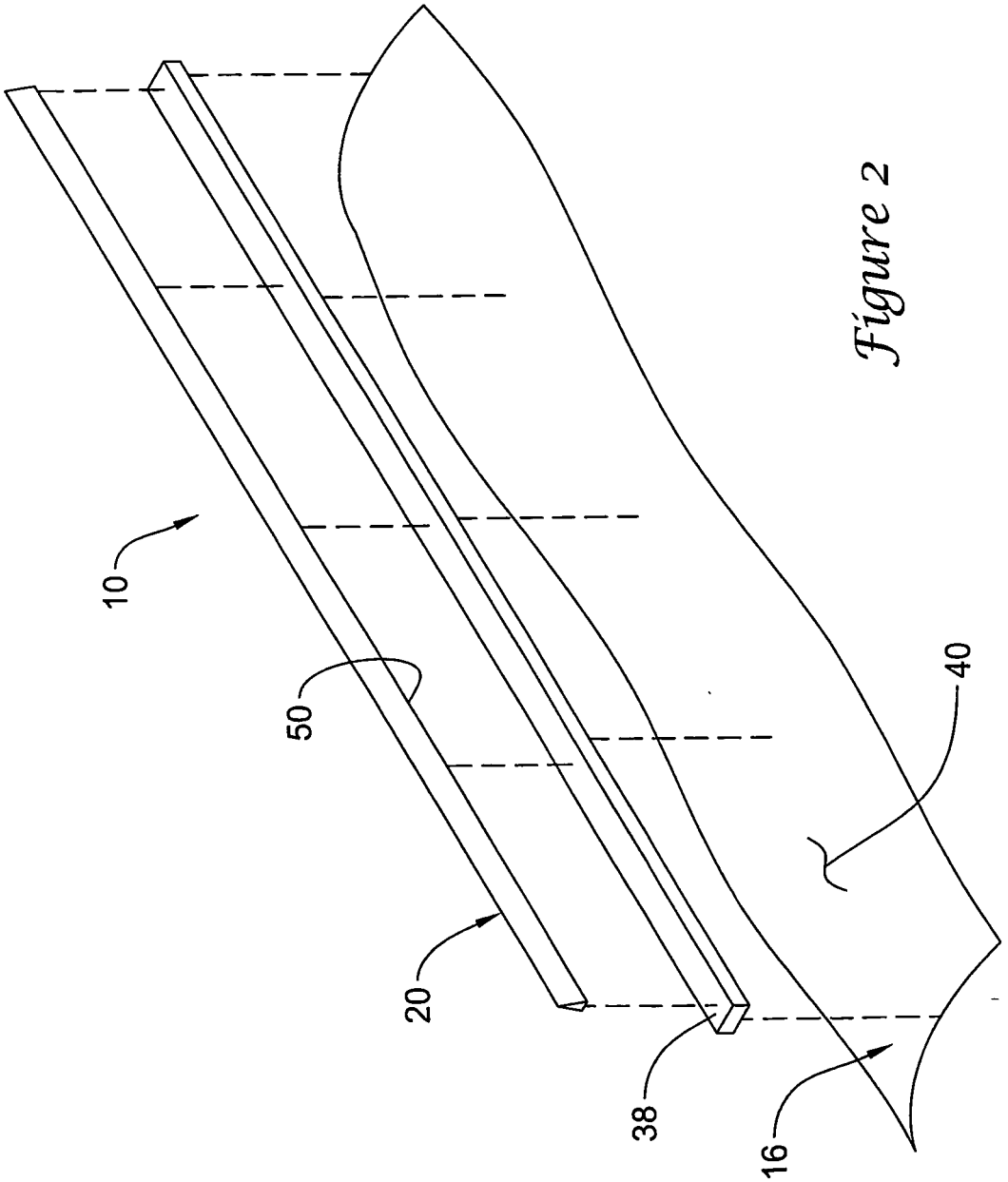

Figure 2

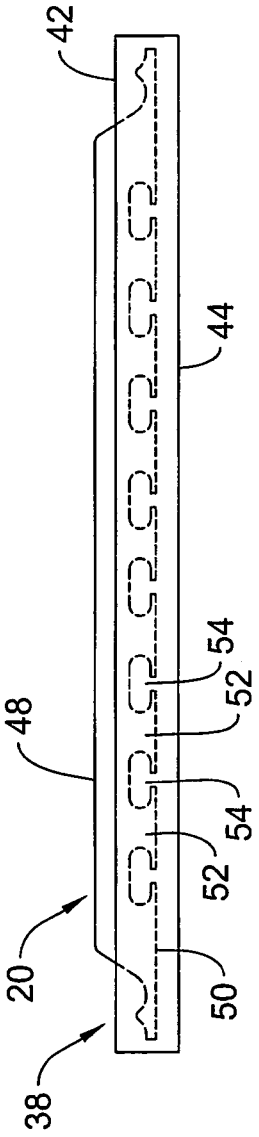

Figure 3

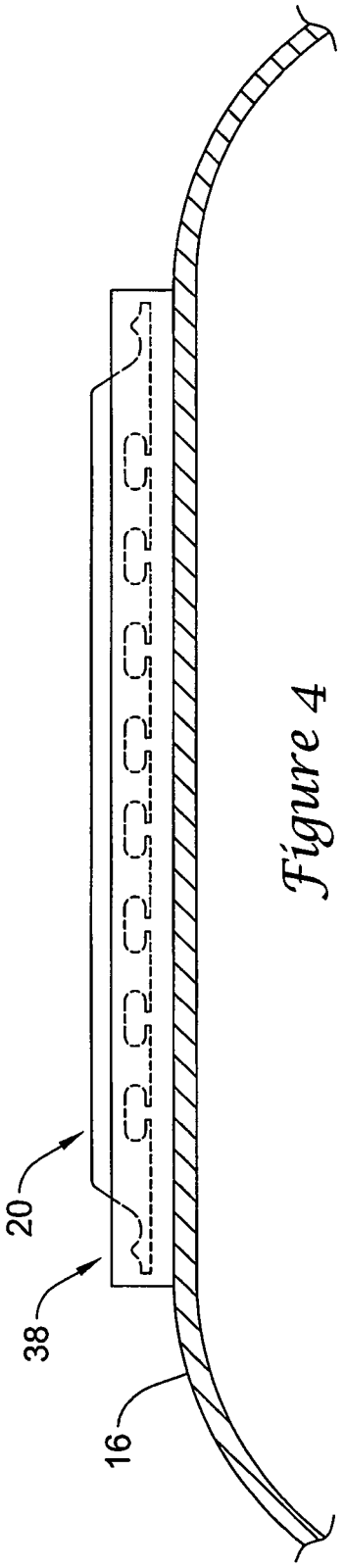

Figure 4

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 5320634 A **[0004]**
- US 6425882 B **[0018]**