(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 June 2003 (26.06.2003)

PCT

(10) International Publication Number
WO 03/051448 A2

(51) International Patent Classification[7]: A61M 25/10, 25/00, A61B 17/22

(21) International Application Number: PCT/US02/40404

(22) International Filing Date:
17 December 2002 (17.12.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/025,670 18 December 2001 (18.12.2001) US

(71) Applicant: **SCIMED LIFE SYSTEMS, INC.** [US/US]; One SciMed Place, Maple Grove, MN 55311 (US).

(72) Inventors: **KOKATE, Jaydeep, Y.**; 7322 Quantico Lane, Maple Grove, MN 55311 (US). **DOBRAVA, Eric, M.**; 11323 Florida Avenue North, Champlin, MN 55316 (US).

(74) Agent: **SCHAEFER, Stephen, R.**; Fish & Richardson P.C., P.A., 60 South Sixth Street, Suite 3300, Minneapolis, MN 55402 (US).

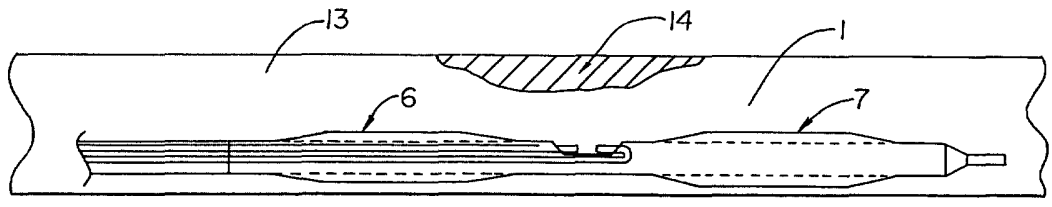
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ASPIRATING DEVICES FOR REMOVAL OF THROMBUS/LIPID FROM A BODY LUMEN



(57) Abstract: Methods and devices for treating vulnerable plaque deposits within a blood vessel, having an inner surface and one or more plaque deposits containing a core material. An exemplary device includes an elongate shaft, a balloon disposed about the elongate shaft for engaging one or more plaque deposits and extracting the core material therefrom, a first venturi section disposed proximally of the balloon, and a second venturi section disposed distally of the balloon. An exemplary method includes the steps of inserting a distal portion of the catheter into a lumen of the blood vessel, positioning the balloon proximate a plaque deposit, inflating the balloon, creating a first stream of fluid proximally of the balloon, collecting the first stream of fluid proximally of the balloon, creating a second stream of fluid distally of the balloon, and collecting the second stream of fluid distally of the balloon.

WO 03/051448 A2

ASPIRATING DEVICES FOR REMOVAL OF THROMBUS/LIPID FROM A BODY LUMEN

Field of the Invention

The present invention relates generally to intravascular catheters. More particularly, the present invention relates to intravascular catheters adapted to treat vulnerable plaque.

Background of the Invention

Therapy modalities for heart disease have traditionally focused on treating blood vessels which have become occluded (blocked) or stenotic (narrowed) by calcified plaque deposits. Blood vessels that have become occluded or stenotic in this manner may interrupt the flow of blood that supplies oxygen to the heart muscle. Occluded or stenotic blood vessels have been traditionally treated with a number of medical procedures including angioplasty and atherectomy. Angioplasty techniques such as percutaneous transluminal angioplasty (PTA) and percutaneous transluminal coronary angioplasty (PTCA) are relatively non-invasive methods of treating restrictions in blood vessels. During these procedures, a balloon catheter is advanced over a guidewire until the balloon is positioned proximate to a restriction in a diseased vessel. The balloon is then inflated and the restriction in the vessel is opened. During an atherectomy procedure, the stenotic lesion is mechanically cut or abraded away from the blood vessel wall using an atherectomy catheter.

Calcified plaque deposits are typically comprised of hard materials. Plaque, however, may also be comprised of soft materials or combinations of soft and hard

materials. Soft plaque is typically comprised of deposits of cholesterol and other fats which build up within the blood vessels as a patient ages. The build up of plaque in the blood vessels is sometimes referred to as atherosclerosis, or hardening of the arteries.

Atherosclerosis often begins as a small injury to an artery wall. This injury triggers a cyclic cascade of injury and response, inflammation, and healing, which may ultimately lead to the narrowing of the artery. As the atherosclerotic plaque worsens, inflammatory cells, especially macrophages, collect at the site to isolate the debris of the damaged tissue. The result is a core of lipid, macrophages or foam cells and nectrotic tissue, covered by a fibrous cap of scar tissue. If the fibrous cap becomes weakened or is subjected to excessive stress, it may rupture, depositing the trombogenic contents of the core into the blood stream. If the resulting blood clot is severe enough, it may occlude the artery. If this obstruction persists in a coronary artery, a myocardial infarction may result.

Plaque deposits that are at risk of rupturing are sometimes referred to as vulnerable plaque. Vulnerable plaque typically comprises a core of soft materials covered with a fibrous cap. Many of vulnerable plaque deposits do not limit the flow of blood through the blood vessels. It is now appreciated that vulnerable plaques that do not limit flow may be particularly dangerous because they produce no warning symptoms, and can rupture suddenly causing a heart attack and death. This may occur, for example, when the vulnerable plaque ruptures and a blood clot is formed inside the blood vessel lumen causing a blockage.

Summary of the Invention

The present invention relates generally to intravascular catheters. One embodiment of the present invention relates to intravascular catheters adapted to treat vulnerable plaque. According to one implementation of the present invention, a catheter for treating a blood vessel having an inner surface and one or more plaque deposits including a core material comprises an elongate shaft having a proximal end and a distal end, a first balloon disposed about a first portion of the elongate shaft for engaging the inner surface of the blood vessel, a second balloon disposed about a second portion of the elongate shaft for engaging the inner surface of the blood vessel, and a first venturi section disposed between the first balloon and the second balloon.

Brief Description of the Drawings

Figure 1 is a perspective view of a distal portion of the catheter in accordance with an exemplary embodiment of the present invention;

Figure 2 is a plan view of the distal portion of the catheter in Figure 1 illustrating one location within the blood vessel where the aspirating device can be used to remove plaque deposits;

Figure 3 is a plan view of the distal portion of the catheter in Figure 1 showing the balloons having an inflated shape engaging the core material from the blood vessel into the venturi section of the catheter;

Figure 4 is an additional plan view of the catheter in Figure 1 illustrating the flow of plaque deposits from the blood vessel into the venturi section of the catheter; and

Figure 5 is a partial cross-sectional view of the catheter system in accordance with an additional exemplary embodiment of the present invention.

Detailed Description of the Invention

The following detailed description should be read with reference to the drawings, in which like elements in different drawings are numbered in like fashion. The drawings, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention. In some cases, the drawings may be highly diagrammatic in nature. Examples of constructions, materials, dimensions, and manufacturing processes are provided for various elements. Those skilled in the art will recognize that many of the examples provided have suitable alternatives that may be utilized.

Figure 1 is a perspective view of a distal portion of a catheter 1 in accordance with the present invention. Catheter 1 includes an elongate shaft 2 having proximal end 3 and distal end 4 which is slideably engaged along delivery sheath 12. A first balloon 6 is disposed about a portion of elongate shaft 2 of catheter 1 proximate first venturi section 5. A second balloon 7 is disposed about a portion of elongate shaft 2 of catheter 1 distal first venturi section 5.

Elongate shaft 2 includes a plurality of walls defining a first tubular member 8 having a first delivery port 10 disposed proximally of balloon 7 and distally of balloon 6. Elongate shaft 2 includes a plurality of walls defining a second tubular member 9 having a first collection port 11 disposed distally of balloon 6 and proximally of first delivery port 10.

Balloons 6 and 7 have an expanded shape, and a contracted shape. Balloons 6 and 7 can be configured such that an engagement surface thereof engages the inner surface of a blood vessel when balloons 6 and 7 assume the expanded shape.

Figure 2 is an additional plan view of the distal portion of catheter 1 illustrated in Figure 1. In the embodiment of Figure 1, balloons 6 and 7 are shown having a deflated shape. Also in the embodiment of Figure 1, distal portion of catheter 1 is disposed within the lumen of a blood vessel 13 containing one or more plaque deposits 14. Catheter 1 is positioned within the lumen of blood vessel 13 such that plaque deposit 14 is located distally of balloon 6 and proximally of balloon 7.

Figure 3 is an additional plan view of the distal portion of catheter 1 illustrated in Figure 1 and Figure 2. In the embodiment of Figure 3, balloons 6 and 7 are shown having an expanded shape. Balloon engagement surface 15 and balloon engagement surface 16 can be adapted for engaging one or more plaque deposits 14 from the inner wall of the blood vessel. In Figure 3, arrows are used to illustrate the movement of core material into venturi section 5 as it is extruded from the plaque deposit by the expansion of balloons 6 and 7 and the contact made by balloon engagement surface 15 and balloon engagement surface 16 against plaque deposit 14.

Figure 4 is an additional plan view of the distal portion of catheter 1 illustrated in figures 1 through 3. In Figure 4, arrows are used to illustrate the movement of core material as it is drawn into second tubular member 9 through venturi section 5 and first collection port 11. In some applications, the presence of core material within blood vessel 18 may cause a thrombus to form. When this is the case, the thrombus can be drawn into tubular member 9 through venturi section 5 and first collection port 11.

Figure 5 is a partial cross-sectional view of a catheter system in accordance with an additional embodiment of the present invention. Catheter system 19 includes a catheter 31 which may be used for treating a blood vessel having an inner surface and one or more plaque deposits that include a core material.

Catheter 31 includes an elongate shaft 41 having proximal end 42 and distal end 43. In the particular embodiment of catheter 31, a balloon 20 comprising a balloon engagement surface 32 is disposed about a portion of elongate shaft 2. Balloon 20 and balloon engagement surface 32 can be adapted for engaging one or more plaque deposits, causing core material to extrude therefrom.

Elongate shaft 2 defines a first tubular member 24 having a first delivery port 23 disposed proximally of balloon 20. Elongate shaft 2 further defines a second tubular member 21 having a first collection port 22 disposed proximally venturi section 30.

Elongate shaft 2 defines a third tubular member 28 having a second delivery port 27 disposed distally of balloon 20. Elongate shaft 2 defines a fourth tubular member 25 having a second collection port 26 disposed proximally venturi section 31.

The second tubular member 21 and fourth tubular member 25 can be used to collect core material that has been extruded from a plaque deposit. The second tubular member 21 and fourth tubular member 24 can be used to collect thrombus.

In the embodiment illustrated in Figure 5, elongate shaft 2 further defines inflation lumen 34 and inflation port 44. Inflation lumen 34 and inflation port 44 are both in fluid communication with chamber 35 defined by balloon 20.

Figure 5 further illustrates a hub 36 disposed about elongate shaft 2 proximate proximal end 42 thereof. In the embodiment of Figure 5, hub 36 includes an inflation

port 38 and vacuum port 39. In Figure 5, fluid source 29 is shown coupled to inflation port 38 of hub 36. Fluid source 29 is capable of injecting fluid into inflation lumen 34, first tubular member 24 and third tubular member 28. In the embodiment of Figure 5, fluid source 29 includes housing 33 defining a variable volume chamber 44 that can be in fluid communication with inflation lumen 34 of elongate shaft 2. In this exemplary embodiment, fluid source 29 further includes a plunger 45 slidingly disposed within variable volume chamber 44. When plunger 45 is depressed proximally, fluid is moved from variable volume chamber 44 through inflation port 38, hub 36, inflation lumen 34 and into chamber 35 of balloon 20, causing the balloon to inflate. It is to be appreciated that catheter system 19 may include various fluid sources without deviating from the spirit and scope of the present invention. Examples of fluid sources that may be suitable in some applications include I.V. bags and peristaltic pumps.

Balloon 20 has an inflated shape and a deflated shape. In Figure 5, balloon 20 is shown in the inflated shape. Balloon 20 may be selectively inflated by injecting fluid from fluid source 29 into chamber 35 of balloon 20. Balloon 20 may be selectively deflated by drawing fluid from chamber 35 of balloon 20 into an inflation fluid reservoir 46.

A vacuum source 40 can be fluidly coupled to vacuum port 39. Vacuum port 39, in turn, is fluidly coupled to second tubular member 21 and fourth tubular member 25. When engaged, vacuum source 40 further aids in collecting plaque deposits from venturi section 30 and venturi section 31.

The elongate shaft 2 may be comprised of a single material, or a combination of materials, without deviating from the scope and spirit of the present invention. For

example, elongate shaft 2 may include an inner tube. The inner tube can be comprised of polytetrafluoroethylene (PTFE). PTFE creates a smooth, low-friction surface for the passage of other devices through elongate shaft 2. Elongate shaft 2 may also include a support member wound or braided around the inner tube. The support member can be comprised of a plurality of filaments. The filaments may be comprised of stainless steel wire. Those with skill in the art will appreciate that other embodiments of a support member are possible without deviating from the spirit and scope of the present invention. For example, a support member may comprise a woven polymer fabric. By way of a second example, a support member may comprise polymer fibers wound in a braided pattern.

Elongate shaft 2 can comprise polyether block amide (PEBA). Polyether block amide is commercially available from Atochem Polymers of Birdsboro, Pennsylvania under the trade name PEBAX. Also, elongate shaft 2 can be fabricated using an extrusion process. In this process, molten PEBA may be extruded onto the combined layers of an inner tube and a support member. When this process is utilized, the extruded material fills any interstitial spaces in the support member.

It is to be understood that other manufacturing processes can be used without departing from the spirit and scope of the present invention. Examples of materials that may be suitable in some applications include: polyethylene (PE), polypropylene (PP), polyvinylchloride (PVC), polyurethane, and polytetrafluoroethylene (PTFE).

Having thus described several embodiments of the present invention, those of skill in the art will readily appreciate that other embodiments may be made and used which fall within the scope of the claims attached hereto. Numerous advantages of the invention

covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of parts without exceeding the scope of the invention.

What is claimed is:

1. A catheter for treating a blood vessel having an inner surface and one or more plaque deposits including a core material, comprising:

an elongate shaft having a proximal end and a distal end;

a first balloon disposed about a first portion of the elongate shaft for engaging one or more plaque deposits from the inner surface of the blood vessel and extracting the core material therefrom;

a second balloon disposed about a second portion of the elongate shaft for engaging one or more plaque deposits from the inner surface of the blood vessel and extracting the core material therefrom; and

a first venturi section disposed between the first balloon and the second balloon.

2. The catheter of claim 1, wherein the first venturi section comprises:

a first tubular member in fluid communication with a fluid source; and

a second tubular member in fluid communication with a fluid reservior.

3. The catheter of claim 2, wherein the first tubular member includes a first delivery port for delivering a first fluid stream; and

the second tubular member includes a first fluid collection port configured such that it receives the first fluid stream.

4. The catheter of claim 2, wherein the first tubular member and the second tubular member comprise hypodermic tubing.

5. The catheter of claim 2, wherein the first tubular member includes a bent portion.

6. The catheter of claim 5, wherein the bent portion of the first tubular member comprises a generally J-shaped portion.

7. The catheter of claim 5, wherein the bent portion of the first tubular member comprises a generally J-shaped portion terminating in a fluid delivery port.

8. The catheter of claim 2, wherein the first tubular member has an inner diameter that is generally smaller than the inner diameter of the second tubular member.

9. The catheter of claim 2, wherein the first tubular member has an inner diameter that is substantially similar to the inner diameter of the second tubular member.

10. A catheter for treating a blood vessel having an inner surface and one or more plaque deposits including a core material, comprising:

an elongate shaft having a proximal end and a distal end;

a balloon disposed about the elongate shaft for engaging one or more plaque deposits from the inner surface of the blood vessel and extracting the core material therefrom;

a first venturi section disposed proximally of the balloon; and

a second venturi section disposed distally of the balloon.

11. The catheter of claim 10, wherein the first venturi section comprises:

a first tubular member in fluid communication with a fluid source; and

a second tubular member in fluid communication with a fluid resevoir.

12. The catheter of claim 10, wherein the second venturi section comprises:

a third tubular member in fluid communication with a fluid source;

a fourth tubular member in fluid communication with a fluid resevoir.

13. The catheter of claim 11, wherein the first tubular member includes a first delivery port for producing a first fluid stream proximally of the balloon; and

the second tubular member includes a first fluid collection port configured such that it receives the first fluid stream.

14. The catheter of claim 11, wherein the first tubular member and the second tubular member are comprised of hypodermic tubing.

15. The catheter of claim 11, wherein the first tubular member includes a bent portion.

16. The catheter of claim 15, wherein the bent portion of the first tubular member comprises a generally J-shaped portion.

17. The catheter of claim 15, wherein the bent portion of the first tubular member comprises a generally J-shaped portion terminating in a fluid delivery port.

18. The catheter of claim 11, wherein the first tubular member has an inner diameter that is generally smaller than the inner diameter of the second tubular member.

19. The catheter of claim 11, wherein the first tubular member has an inner diameter that is substantially similar to the inner diameter of the second tubular member.

20. The catheter of claim 12, wherein the third tubular member includes a third delivery port for producing a second fluid stream distally of the balloon; and

the fourth tubular member includes a second fluid collection port configured such that it receives the second fluid stream.

21. The catheter of claim 12, wherein the third tubular member and the fourth tubular member are comprised of hypodermic tubing.

22. The catheter of claim 12, wherein the third tubular member includes a bent portion.

23. The catheter of claim 22, wherein the bent portion of the third tubular member comprises a generally J-shaped portion.

24. The catheter of claim 22, wherein the bent portion of the third tubular member comprises a generally J-shaped portion terminating in a fluid delivery port.

25. The catheter of claim 12, wherein the third tubular member has an inner diameter that is generally smaller than the inner diameter of the fourth tubular member.

26. The catheter of claim 12, wherein the third tubular member has an inner diameter that is substantially similar to the inner diameter of the fourth tubular member.

27. A method for treating vulnerable plaque deposits within a blood vessel having an inner surface and one or more plaque deposits containing a core material, comprising the steps of:

providing a catheter with an elongate shaft having a proximal end and a distal end, a first balloon disposed about a portion of the elongate shaft for engaging one or more plaque deposits and extracting the core material therefrom, a second balloon disposed about a portion of the elongate shaft distal for engaging one or more plaque deposits and extracting core material therefrom, and a first venturi section disposed between the first and second balloons;

inserting a distal portion of the catheter into the lumen of a blood vessel;

positioning the first balloon proximate to, and the second balloon distal to, a plaque deposit;

inflating the balloons;

delivering a first stream of fluid to the first venturi section; and

collecting the first stream of fluid.

28. A method for treating vulnerable plaque deposits within a blood vessel, having an inner surface and one or more plaque deposits containing a core material, comprising the steps of:

providing a catheter with an elongate shaft having a proximal end and a distal end, a balloon disposed about the elongate shaft for engaging one or more plaque deposits and extracting the core material therefrom, a first venturi section disposed proximally of the balloon, and a second venturi section disposed distally of the balloon;

inserting a distal portion of the catheter into the lumen of a blood vessel;

positioning the balloon proximate a plaque deposit;

inflating the balloon;

delivering a first stream of fluid proximally of the balloon and a second stream of fluid distally of the balloon; and

collecting the first stream of fluid proximally of the balloon and the second stream of fluid distally of the balloon.

29. The method of claim 28, further including the steps of creating a third stream of fluid distally of the balloon and collecting the third stream of fluid distally of balloon.

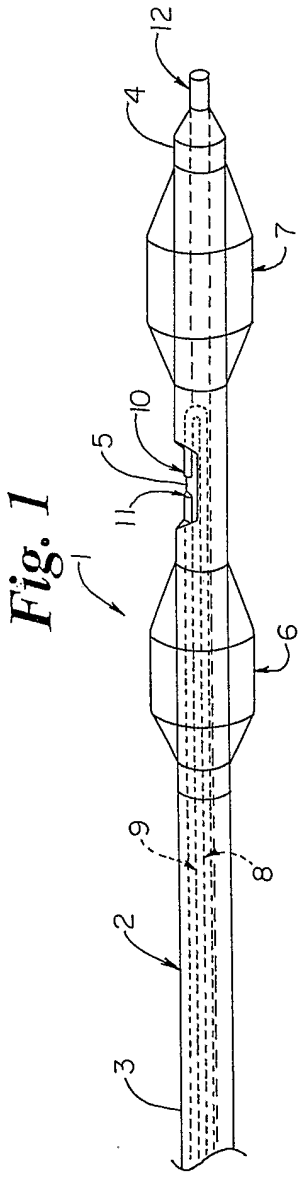


Fig. 1

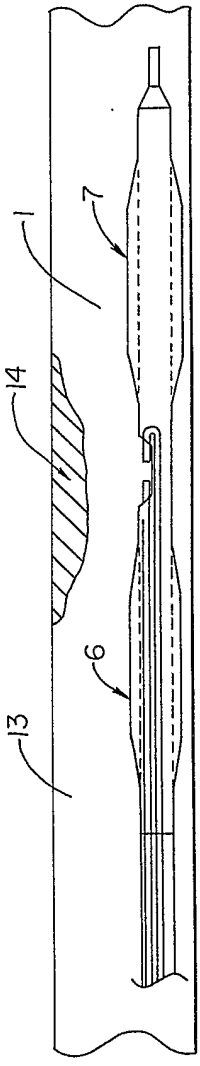


Fig. 2

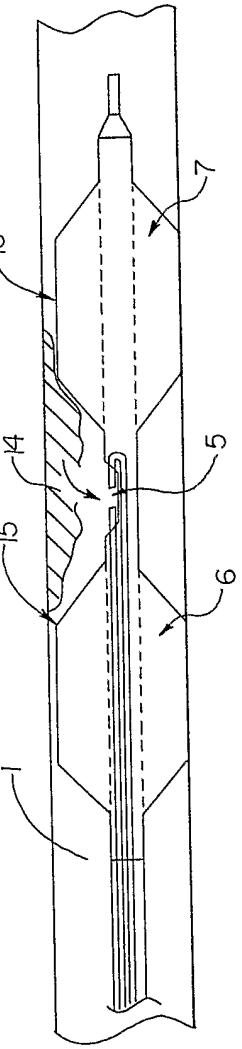


Fig. 3

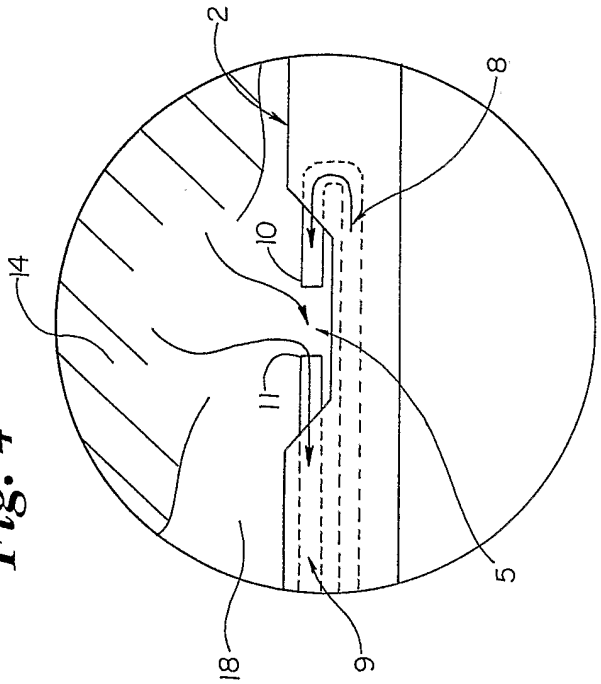


Fig. 4

Fig. 5