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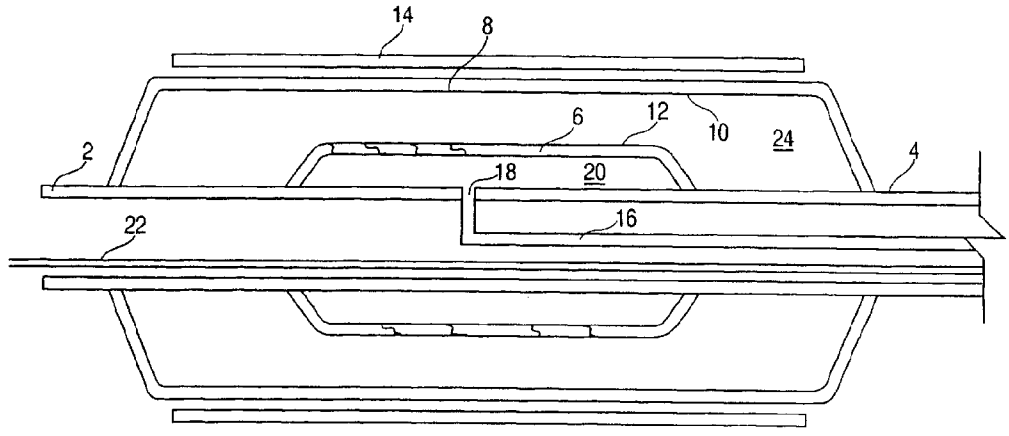
(54) Title: TWO BALLOON CATHETER FOR STAGED STENT EXPANSION



(57) Abstract: A catheter with two balloons for implanting a stent without flaring at the ends of the stent during implantation has an outer balloon overlying an inner balloon. The length of the inner balloon is shorter than the length of the outer balloon and shorter than a stent which is mounted over both balloons. Upon inflation of the inner balloon, the inner balloon expands only the center of the stent. After the center of the stent is expanded, further application of pressure bursts the inner balloon allowing application of pressure to the outer balloon. The outer balloon is then inflated, expanding the ends of the stent.

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TWO BALLOON STAGED STENT EXPANSION

FIELD OF THE INVENTION

The present invention relates generally to catheter balloons for implanting stents. More particularly, the present invention relates to a catheter balloon which utilizes two balloons coaxially disposed within one another.

BACKGROUND OF THE INVENTION

Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

It is well known to use a balloon catheter to intraluminally deliver and implant a stent. Typically, to implant a stent with a balloon catheter, the unexpanded stent is disposed around the deflated balloon of a balloon catheter. The balloon is then delivered to the desired implantation site and inflated. The inflation of the balloon expands the stent, implanting it at the desired location.

One shortcoming of conventional balloon catheters is that they may cause the ends of the stent to flare out during implantation. This flaring out is referred to as "dogboning". Dogboning causes at least two undesirable effects. First, dogboning exacerbates any foreshortening of the stent during expansion. Second, dogboning causes the edges of the end of the stent to project in a direction perpendicular to the wall of the vessel in which the stent is being implanted. These projecting edges potentially increase trauma to the wall of the lumen.

It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

SUMMARY OF THE INVENTION

According to one aspect of the invention there is provided a stent and balloon catheter in combination comprising:

a balloon catheter with a first and a second balloon, the second balloon overlaying the first balloon, the second balloon having a length which is greater than a length of the first balloon; and

an expandable stent mounted over the first and second catheter balloons,

wherein a burst pressure of the first balloon is less than a burst pressure of the second balloon.

Unless the context clearly requires otherwise, throughout the description and the claims, the words 'comprise', 'comprising', and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

According to another aspect of the invention there is provided a method of implanting a stent, comprising:

first expanding the central area of the stent with a first balloon;

bursting the first balloon; and

then expanding the ends of the stent with a second balloon.

To implant the stent, the catheter is delivered to a desired site in a vessel. Pressure is applied to the inner balloon, inflating the balloon and implanting the central portion of the stent. Further increases in pressure rupture the inner balloon. Because the outer balloon overlays the inner balloon, the pressure inflates the outer balloon, expanding the remainder of the stent. The balloons may then be deflated and removed, leaving the implanted stent in the vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

A preferred embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Fig. 1 shows a cross-sectional view of an embodiment of a catheter balloon assembly constructed according to the principles of the present invention which is in the deflated condition;

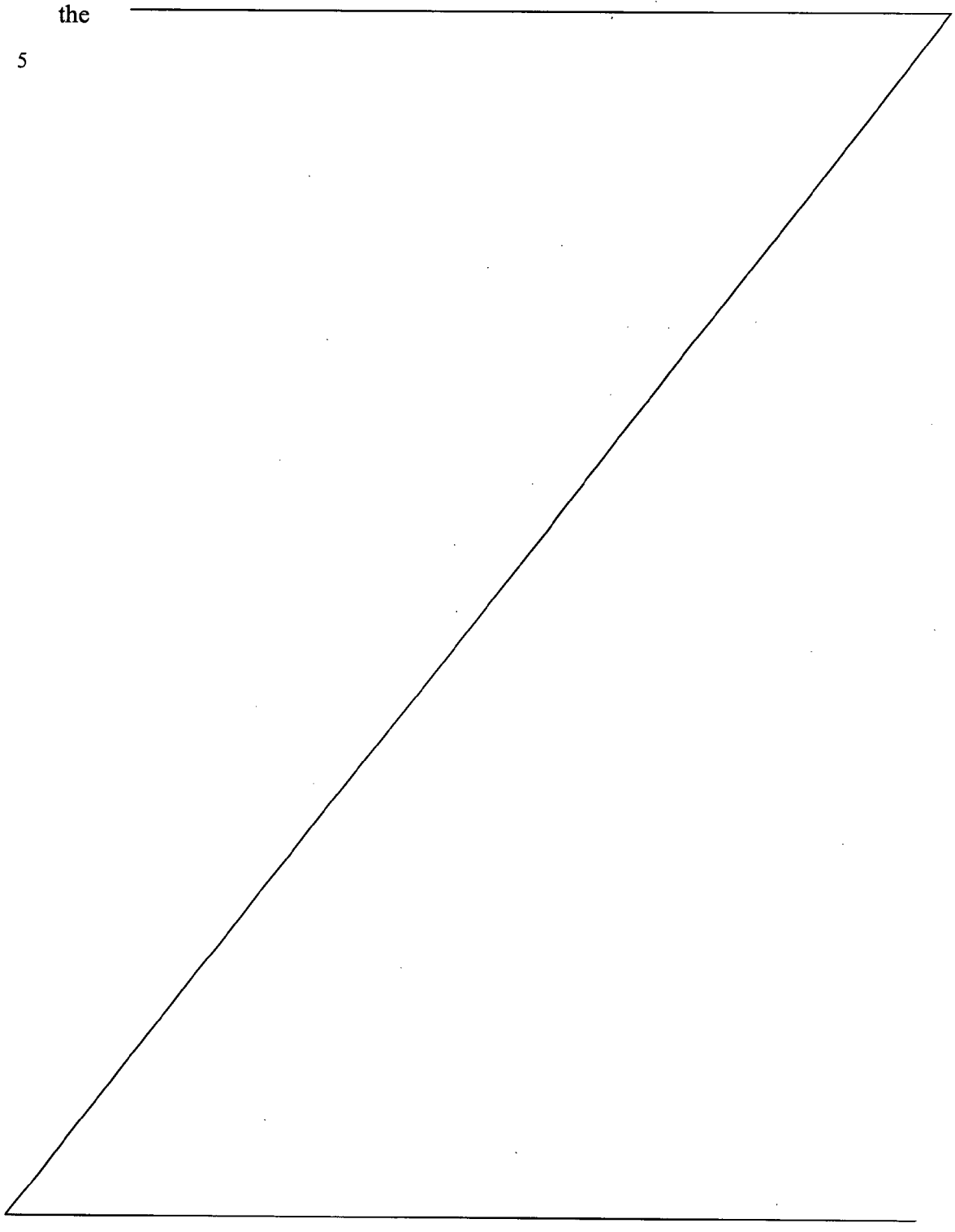
Fig. 2 shows a cross-sectional view of the catheter of Fig. 1 after partial inflation; and

Fig. 3 shows a cross-sectional view of the catheter of Fig. 1 after full inflation.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 shows a schematic view of an embodiment of a catheter balloon constructed in accordance with the principles of the present invention. The details of the catheter have not been included here, as they are well known to those skilled in the art. The precise configurations of the catheter shaft, guidewire lumen, and inflation lumen can be

chosen as desired. For example, the catheter may be designed as a rapid-exchange system or as an over-the-wire system. The balloon catheter includes a catheter shaft 2. An inner balloon 6 is sealed to the outer surface 4 of the catheter shaft 2. The length of the



inner balloon is chosen so that it is less than the length of the stent which it is designed to implant. The inner balloon 6 may be formed of a non-compliant material.

An outer balloon 8 is disposed around the inner balloon 6. The inner surface 10 of the outer balloon is immediately adjacent to the outer surface of the inner balloon. The two surfaces are permitted to move with respect to each other. The outer balloon 8 is sealed to the outer surface 4 of the catheter shaft 2 at the ends of the balloon. The outer balloon 8 may be formed of a non-compliant material. In the illustrated embodiment, the length of the outer balloon is chosen so that it is approximately 4 mm longer than the stent. In this and other embodiments, when the stent is crimped around the deflated balloon, the same amount of balloon may extend past the stent on each side - - i.e. the balloon may, for example, extend past the stent by 2mm on each side.

An inflation lumen 16 is located within the catheter shaft 4. The inflation lumen 16 is in fluid communication with the interior 20 of the inner balloon 6 through an aperture 18 in the catheter shaft 4. A pressurized medium, such as saline, may be introduced into the inflation lumen 16 to inflate the inner balloon. The space between the inner balloon and the outer balloon is not provided with an inflation lumen.

In operation, a guidewire 22 may be routed to the desired inflation location. The balloon catheter, the catheter shaft 4 of which has a guidewire port located adjacent the balloons, with a crimped stent may be then placed over the guidewire 22 and delivered to the desired location. A pressurized medium is introduced into the inflation lumen. The pressurized medium passes into the interior 20 of the inner balloon 6, and begins to inflate the inner balloon 6. The inner balloon 6 applies pressure to both the stent 14 and the outer balloon 8. Typically,

at approximately 3 or 4 atmospheres (depending on the particular stent design chosen), the stent 14 begins to expand. As shown in Fig. 2, because the inner balloon 6 is shorter than the stent 14, only the middle portion of the stent 14 begins to expand. At, for example, approximately five atmospheres, the stent 14 is sufficiently expanded so that it is implanted into the vessel wall.

As shown in Fig. 3, upon further application of the pressurized medium to the inflation lumen, the inner balloon 6 ruptures. The burst pressure of the inner balloon may be less than 10 atmospheres, and in some embodiments be approximately 5 atmospheres, for example. Rupture of the inner balloon 6 allows fluid communication between the inflation lumen 16 and the cavity formed between the outer balloon and the inner balloon.

When further pressure is applied to the inflation lumen, the outer balloon expands the entire length of the stent. The operator may then apply as much pressure as desired, up to the burst pressure of the outer balloon to firmly implant the stent. Typically, the burst pressure of the outer balloon should be greater than that of the inner balloon. Thus, for example, in a particular embodiment the burst pressure of the inner balloon may be selected to be, for example, 5 atmospheres, and the burst pressure of the outer balloon may be selected to be equal to 10 atmospheres, *i.e.*,to give an approximately 5 atmosphere difference.

The balloons may then be deflated, and the catheter and guidewire may then by removed.

In the foregoing specification, the invention has been described with reference to specific exemplary embodiments. It will, however, be evident that various modifications and changes may be made thereunto without departing from the broader spirit and scope of the invention as set forth in the appended claims. The specification and drawings are

accordingly to be regarded in an illustrative rather than a restrictive sense.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A stent and balloon catheter in combination comprising:

a balloon catheter with a first and a second balloon, the second balloon overlaying the first balloon, the second balloon having a length which is greater than a length of the first balloon; and

an expandable stent mounted over the first and second catheter balloons,

wherein a burst pressure of the first balloon is less than a burst pressure of the second balloon.

2. The combination according to claim 1 wherein the burst pressure of the inner balloon is less than 10 atmospheres.

3. The combination according to claim 1 or claim 2 wherein the burst pressure of the inner balloon is approximately 5 atmospheres.

4. The combination according to claim 1, 2 or 3 wherein the burst pressure of the outer balloon is greater than 10 atmospheres.

5. The combination according to any of claims 1-4 wherein the outer balloon is formed of a non-compliant material.

6. The combination according to any of claims 1-5 wherein the inner balloon is formed of a non-compliant material.

7. The combination according to any of claims 1-6 wherein the catheter shaft has a guidewire port located adjacent the balloons.

8. The combination according to any of claims 1-7 wherein the burst pressure of the first balloon is at least 5 atmospheres less than the burst pressure of the second balloon.

9. The combination according to any of claims 1-8 wherein a length of the first balloon is less than a length of the stent.

10. The combination according to any of claims 1-9 wherein a length of the second balloon is greater than a length of the stent.

11. A method of implanting a stent, comprising:

first expanding the central area of the stent with a first balloon;

bursting the first balloon; and

then expanding the ends of the stent with a second balloon.

12. The method of claim 12 wherein said first balloon comprises an inner balloon disposed inside said second balloon which comprises an outer balloon.

13. The method of claim 11 or 12 comprising:

mounting a stent on a balloon catheter with the outer balloon overlaying the inner balloon, a burst pressure of the inner balloon being substantially less than a burst pressure of the outer balloon;

delivering the balloon catheter and stent to a desired location in a vessel in a body;

inflating the inner balloon to a pressure sufficient to expand the stent;

continuing inflating the inner balloon to a pressure sufficient to burst the inner balloon prior to inflating said out balloon;

inflating the outer balloon to a pressure sufficient to implant the stent; and

deflating and removing the balloon catheter.

14. The method according to claim 13, wherein said step of delivering comprises delivering over a guide wire.

15. The method according to claim 13 or 14, wherein the step of inflating the inner balloon to a pressure sufficient to expand the stent implants the central portion of the stent and said step of inflating the outer balloon to a pressure sufficient to implant the stent implants the ends of the stent.

16. The method according to any of claims 13-15, wherein a burst pressure of the outer balloon is over approximately 10 atmospheres and a burst pressure of the inner balloon is less than approximately 5 atmospheres.

17. The method according to any of claims 13-16, wherein the outer balloon has a length longer than the stent and the inner balloon has a length shorter than the stent.

18. A stent and balloon catheter in combination substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings and/or examples.

19. A method of implanting a stent substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings and/or examples.

DATED this 17th day of March, 2004

BALDWIN SHELSTON WATERS

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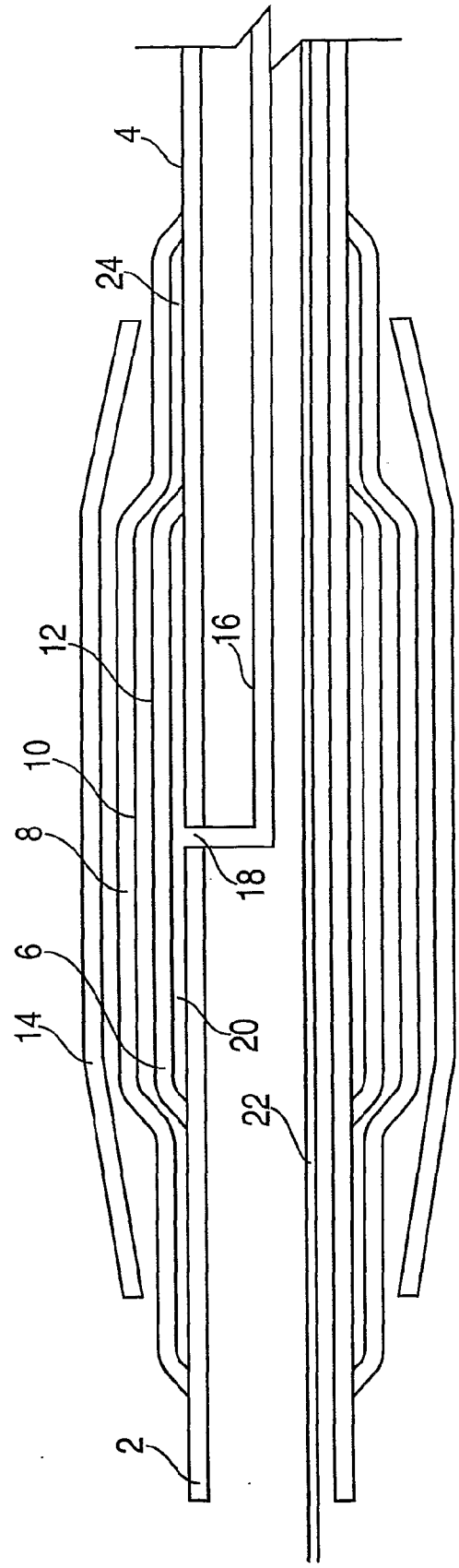

FIG.1

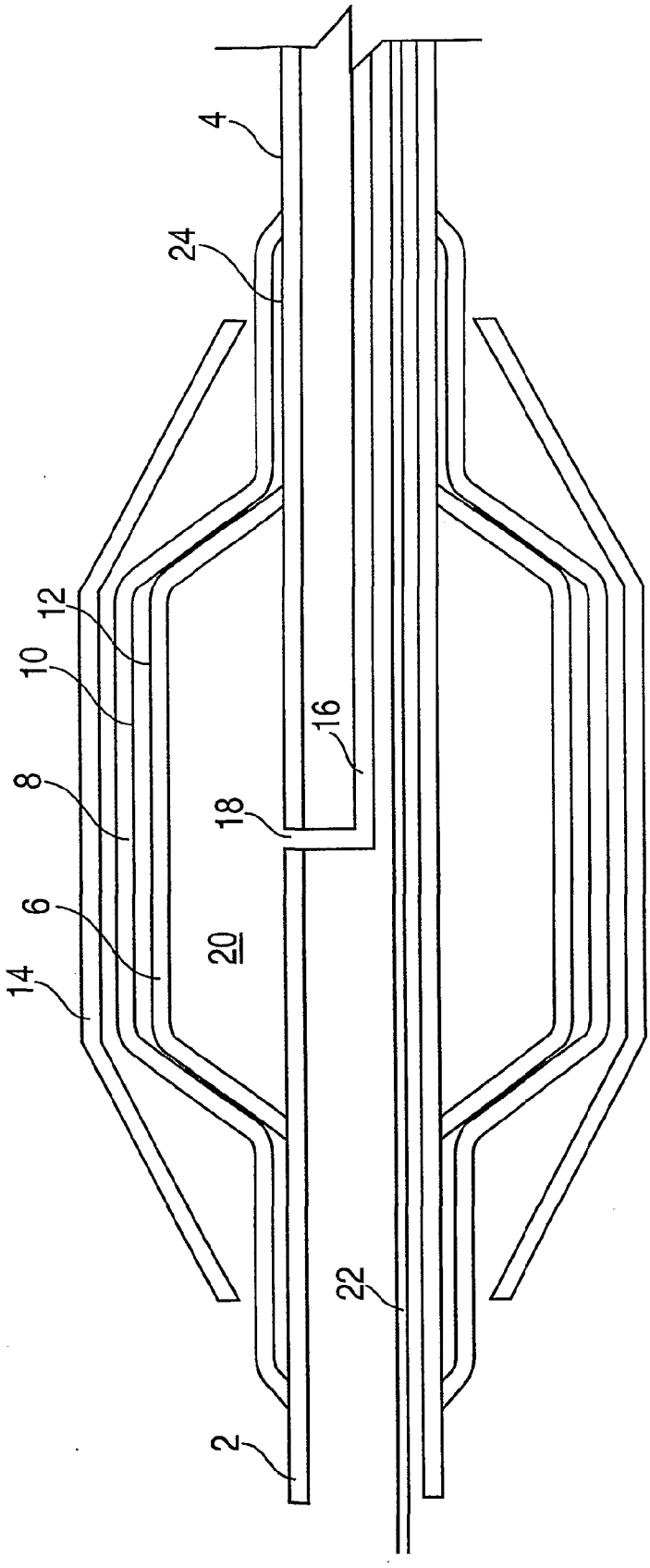

FIG. 2

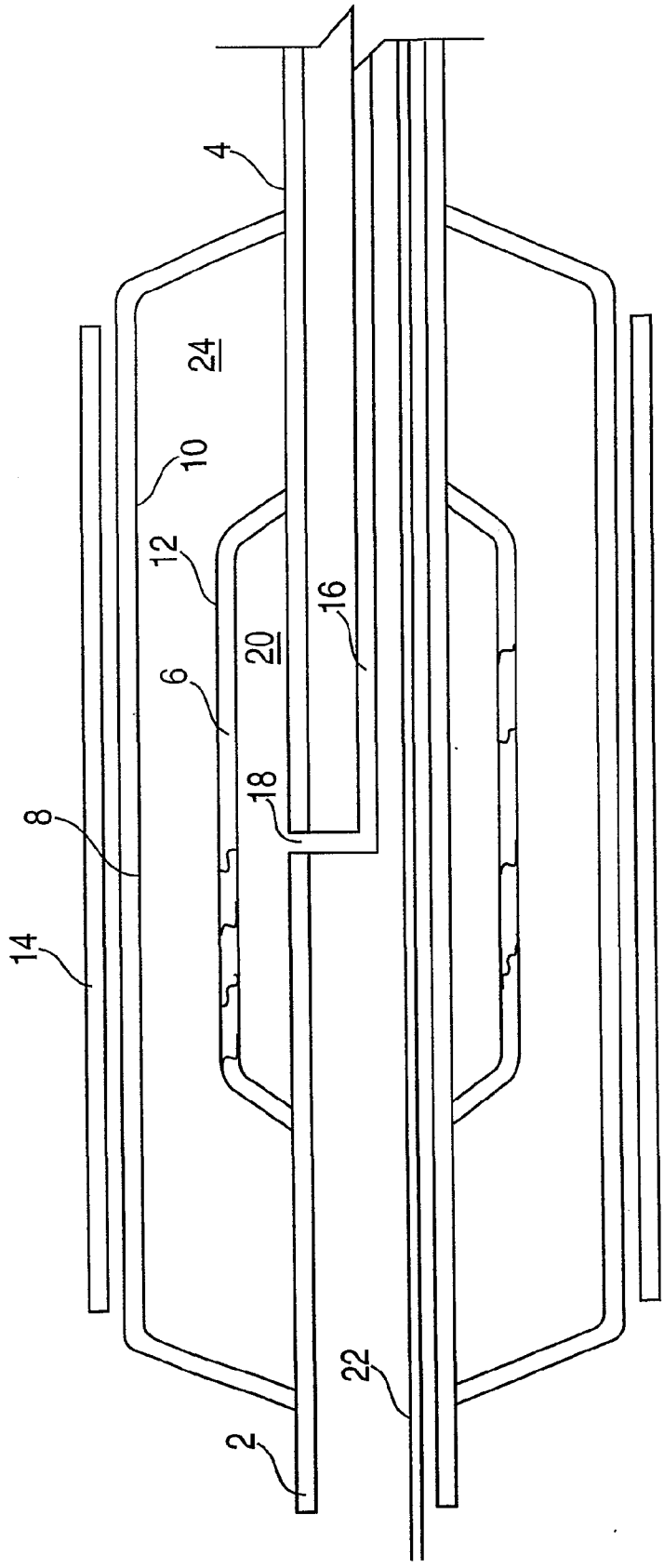

FIG. 3