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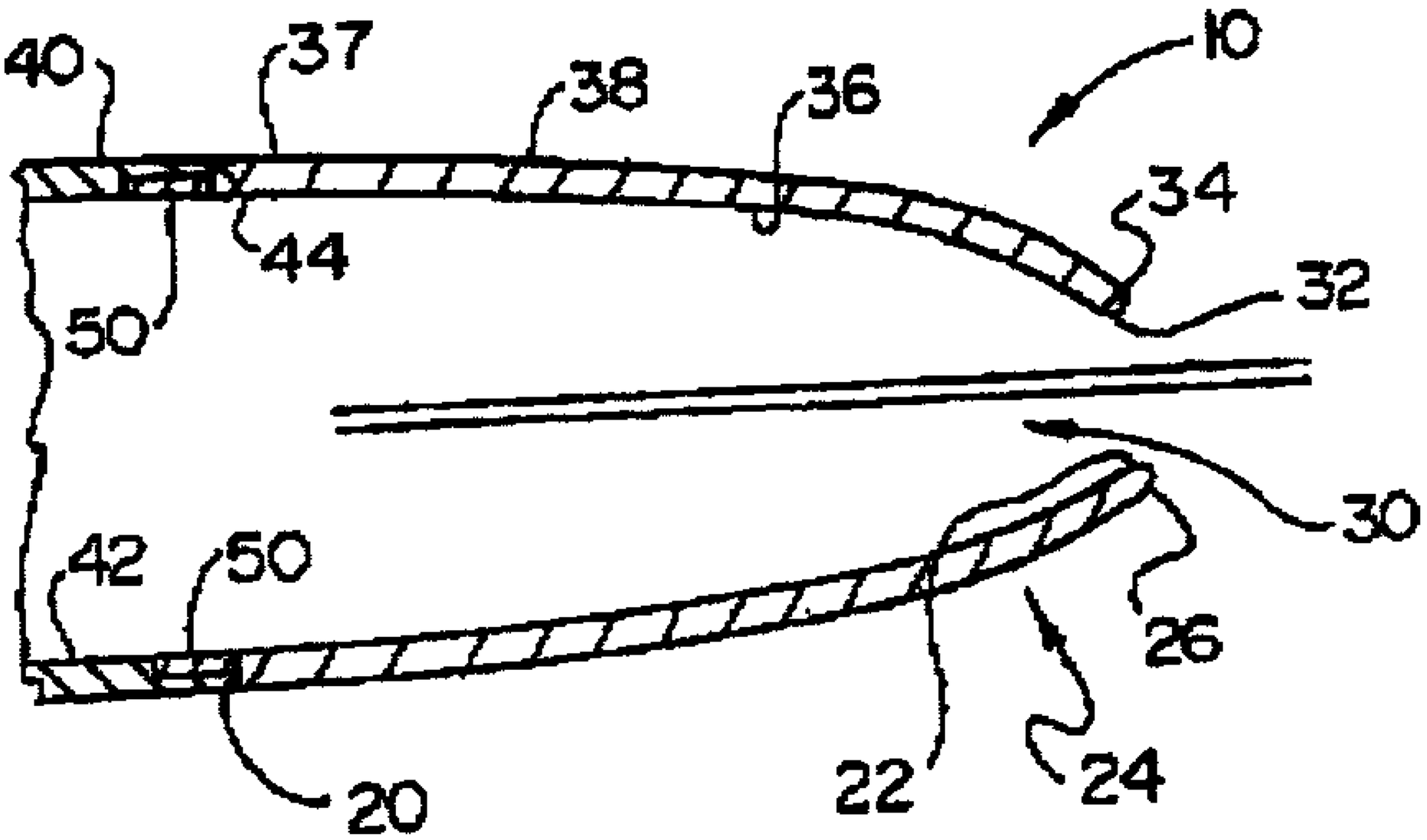
(54) Title: ROLLED TIP RECOVERY CATHETER



(57) Abrégé/Abstract:
A distal tip for use with a medical catheter. The tip includes a member having a wall which defines a lumen therewithin. The wall has a portion at a distal end thereof, the portion curving inwardly toward an axis of the lumen. The lumen is provided with a diameter adaptable to accommodate a device to be recovered therewithin.

ABSTRACT

A distal tip for use with a medical catheter. The tip includes a member having a wall which defines a lumen therewithin. The wall has a portion at a distal end thereof, the portion curving inwardly toward an axis of the lumen. The lumen is provided with a diameter adaptable to accommodate a device to be recovered therewithin.

ROLLED TIP RECOVERY CATHETER

CROSS REFERENCE TO RELATED APPLICATIONS

This is a regular application filed under 35 U.S.C. § 111(a) claiming priority, under 35 U.S.C. § 119(e)(1), of provisional application Serial No. 60/268,773, previously filed February 14, 2001 under 35 U.S.C. § 111(b).

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to the field of medical catheters. More specifically, the present invention relates to recovery catheters used in distal embolic protection.

2. Description of the Related Art

Medical catheters are commonly employed for use in a lumen of a patient's body. The catheter enters the patient's body at an access site and is advanced through the lumen to a treatment site. The lumen may be in the patient's vascular system, such as that in a blood vessel, and the treatment site may be a stenosed region where a portion of the lumen is narrowed due to build-up of material on the lumen wall. Such narrowing is known as a stenosis.

The catheter may be guided to the treatment site through utilization of a guidewire. The guidewire typically is an elongated member having a distal end and a proximal end. The guidewire enters the patient's body at the access site and is advanced through the lumen to the treatment site. The distal

end of the guidewire is the end nearest the treatment site, whereas the proximal end is the end nearest the access site. The guidewire may be positioned in proximity to the treatment site such that the distal end of the guidewire is moved to the proximal side of the treatment site (i.e., the side of the treatment site nearest the access site). The distal end of the guidewire may then cross the treatment site, thereby positioning the distal end of the guidewire on the distal side of the treatment site (i.e., the side of the treatment site farthest from the access site).

Generally, catheters comprise an elongated tubular body having a central lumen in which a guidewire can be received. The catheter is advanced along the guidewire for positioning at the treatment site. The catheter has a distal end that is advanced through the lumen of the patient's body to the treatment site.

The catheter body may have a diameter that makes it particularly difficult to advance the catheter across the treatment site if a stenosis has significantly narrowed the lumen. The prior art addresses this problem by providing a distal tip of the catheter which is tapered radially inwardly in the distal direction. Such a tapered distal tip allows for the catheter to be advanced through a narrowed portion of the lumen.

Another problem that may occur is that the catheter can become caught on a stent. A stent, generally, is a tubular wire structure that is positioned within a stenosis to maintain the lumen diameter. When a catheter is advanced across an area having a stent, the distal tip may engage an edge of the stent which can prevent further advancement of the catheter. Catheter advancement past a stent can be especially

problematic when the stent is implanted in a curved vessel, or when the stent is underexpanded or incompletely deployed. This problem has been addressed by the prior art by rounding the distal tip or tapering the distal tip down to the approximate outer diameter of the guidewire in order to minimize the surface area available for engagement of the stent. This approach also provides for a gradual transition from the wire diameter to the catheter outer diameter, and tends to center the catheter in relation to the stent to facilitate stent crossing.

Some devices, such as embolic protection devices, may have a host wire that acts as a guidewire for other devices including catheters. An embolic protection device is a collapsible/expandable filter affixed to the distal portion of a guidewire. In the collapsed state, the embolic protection device is compressed toward the guidewire to give the device a smaller diameter so that it can be advanced within the lumen. In the expanded state the embolic protection device deploys outwardly from the guidewire such that it engages the wall of the lumen and acts as a filter by allowing fluid, such as blood, to pass therethrough while preventing emboli or particulate matter entrained in the fluid from passing therethrough. Emboli or particulate matter may become entrained in the fluid when a stenosis is being treated. Such particles of the stenosis may become dislodged due to contact with a treatment apparatus. Such treatments may include ablation procedures such as thrombectomy and atherectomy procedures, balloon angioplasty, stenting, and the like.

After treatment, the embolic protection device is typically collapsed in a manner wherein it maintains the captured emboli as the device is removed from the lumen. To

prevent the release of the emboli back into the fluid, it is preferred to enclose the embolic protection device within a catheter. The collapsed embolic protection device has a proximal periphery that is greater than that of the outer diameter of the guidewire. Prior art catheters for receiving an embolic protection device have a relatively large diameter so as to receive the captured emboli containing protection device. Such catheters can be difficult to advance through a narrowed portion of a vessel or may become caught on a stent. If such catheters are provided with tapered tips, as described above, it becomes difficult to receive an emboli filled protection device within the catheter due to the small diameter of the tapered catheter tip. Alternatively, if prior art catheters are made small in diameter to facilitate stent crossing, it is possible that captured embolic material will be extruded through the distalmost part of the protection device filter during withdrawal of the emboli filled protection device into the small diameter catheter.

It would be advantageous to provide a catheter having a distal tip that allows passage of the catheter through a narrowed or stented portion of a lumen, while being able to receive an embolic protection device therein.

SUMMARY OF THE INVENTION

The present invention is an improved catheter for use in recovery of an embolic protection device. It is intended for use in a lumen of a patient's body such as a blood vessel. A distal tip of the catheter permits facile advance through a narrowed portion of the blood vessel, such as a stenosed region, and can conform in a manner to receive, for example,

an embolic protection device having a diameter greater than the inner diameter of the distal tip.

An object of the invention is to provide a catheter that can cross stents or poorly deployed stents and yet can conform in a manner to receive an embolic protection device having a diameter greater than the inner diameter of the distal tip.

Another object of the invention is to provide a catheter that can cross stents or poorly deployed stents and yet can receive an embolic protection device without causing extruded emboli.

Yet another object of the invention is to provide a catheter with a large volume capacity that can cross stents or poorly deployed stents.

Yet another object of the invention is to provide a catheter tip that expands radially while receiving an embolic protection device having a diameter greater than the inner diameter of the distal tip.

The current invention comprises a tubular member having an inner diameter positionable over a guidewire having a device, such as an embolic protection device, carried proximate the distal end thereof. The distal tip is formed of a compliant material and has an inner diameter less than the diameter of a deployed embolic protection device. The material adapts to conformingly receive the protection device therein as the device is drawn into a lumen in the distal tip.

A preferred embodiment of the present invention comprises a distal tip attached to a main catheter body. The distal tip is defined by a body having a taper decreasing in a direction toward the distal end. The tubular body defines a wall forming a lumen therein. At the distal end, the wall of the body curves inward toward the lumen, thus forming a rolled

tip. The distal tip is made of a compliant material that adapts to conformingly receive a device such as an embolic protection device.

DESCRIPTION OF THE DRAWING FIGURES

FIG. 1 is a side sectional view of a distal tip in accordance with the present invention mounted to the distal end of a catheter;

FIG. 2 is a view, similar to FIG. 1, illustrating an alternative embodiment;

FIG. 3 is a view of the present invention illustrating a distal protection device beginning to be drawn therewithin;

FIG. 4 is a view similar to FIG. 3 illustrating the protection device being drawn into the distal tip and deforming the distal end thereof;

FIG. 5 is a view similar to FIGS. 3 and 4 illustrating the distal tip having captured the protection device.

DETAILED DESCRIPTION OF THE INVENTION

The device shown in FIG. 1 is suitable for use on a medical recovery catheter. The distal tip 10 comprises a tapered member. The member has a wall 34 that defines a lumen 30. The lumen 30 extends through the length of the distal tip 10. The lumen 30 extends from the proximal end 20 of the distal tip 10 to the distal end 24 of the distal tip 10 to form an aperture through the distal tip 10. The distal end 24 is the end located farthest from the attachment to the main catheter body 40, and the proximal end 20 is the end located nearest the catheter body 40.

A catheter body 40, suitable for use with the present invention, is a tubular member that has a lumen therethrough. The catheter lumen is in communication with the lumen 30 of the distal tip 10. The catheter lumen 42 is in communication with the lumen 30 of the distal tip 10 when the distal end 44 of the catheter is connected to the proximal end 20 of the

distal tip 10. The catheter body may optionally contain a radiopaque marker band 50 in the general vicinity of the distal end 44 of the catheter. The radiopaque marker band may be entirely within the catheter body 40, entirely within the proximal portion of the distal tip, or any combination thereof.

The wall 34 of the distal tip 10 has a given thickness. The wall thickness can be uniform or be tapered. In one embodiment, the wall 34 has a taper decreasing to a lesser thickness as the wall progresses in the distal direction as shown in Fig. 2.

The lumen 30 of the distal tip 10 can have a uniform diameter along the length of the distal tip 10 or it may be tapered. In one embodiment, the lumen of the distal tip 30 tapers narrowingly in the distal direction. Thus, the lumen diameter can decrease as it progresses in the distal direction.

The distal end 24 of the distal tip 10 can have a rolled tip as at 32. The portion of the wall 34 at the distal end 24 of the distal tip 10 can be rolled inward toward the axis 52 of the lumen 30 to form the rolled tip 32.

The wall 34 of distal tip 10 has an inside surface 36 and an outer surface 38. At the rolled tip 32, end 22 is shown as facing inwardly toward the lumen 30. The end 22 is facing generally radially inwardly. The outer surface 38, over most of the length of the distal tip 10, faces generally radially outwardly. However, at the rolled tip 32, the outer surface 38 is curved so as to face in the distal direction to define a distal contact surface 26.

The present invention can be used in the lumen of a human body, such as in a blood vessel 54. The rolled tip 32 is

especially designed for crossing a stented or otherwise constricted region of a blood vessel 54. A stent is a generally tubular member having a wire wall defining the boundary of the blood vessel lumen. The catheter must pass through the lumen defined within the stent in order to cross the stented region. As a catheter in accordance with the prior art is advanced within the blood vessel, the distal end of the catheter can become caught against an axial end of the stent. This is particularly true at a curve in the blood vessel 54, or when the stent is underexpanded or incompletely deployed. More specifically, the end of the catheter may engage an axial end of the stent. This can prevent the catheter from being able to advance farther into the blood vessel 54. Similar problems may occur in a constricted or stenosed region of a blood vessel.

The rolled tip configuration in accordance with the present invention can prevent such problems. A catheter utilizing the distal tip 10, having a rolled tip 32 described herein, is inserted into a blood vessel. The distal tip 10 is advanced to a stented region of the blood vessel. The rolled tip 10 is curved, as previously discussed, such that the outer portion of the wall 34 at the rolled tip 32 defines contact surface 26. As the distal tip 10 is advanced through the region, the contact surface 26 of the rolled tip 32 may engage a stent. The rolled tip 32 prevents the distal tip 10 from becoming impassibly engaged with the stent. As the distal tip 10 is urged across the stented region, the rolled tip 32 may contact the stent, but it will deflect from the point of contact and be urged away from the stent. Thus, where the outer surface 38 contacts the stent, the distal tip 10 can continue advancing past the stent as a result of non-

engagement with the axial end of the stent and allowing the distal tip 10 to continue advancing within the blood vessel 54.

The distal tip 10 can also function to capture, for example, a protection device 58 within the lumen 30. Lumen 30 is of a given diameter. The distal tip 10 is connected to a catheter such that the distal tip lumen 30 is in smooth communication with a catheter lumen 42.

A device 58 to be captured within the lumen 30 might be, for example, an embolic protection device. A guidewire extends proximal with respect to the protection device 58, extending through the lumen 30 of the distal tip 10 and catheter 40. The device is typically positioned distal to the distal tip 10 and is secured to the guidewire. The protection device 58 has a diameter that is typically greater than that of the distal tip distal end 24.

Again, the distal tip 10 is made of a compliant material such that the protection device 58 can be facilely received into the distal tip lumen 30. As the protection device 58 is drawn toward the distal tip 10, it will first contact the rolled tip 32 at the contact surface 26. The rolled tip 32 may be urged elastically inward as the device enters the lumen 30 (Fig. 3). After the device 58 has been fully drawn in the proximal direction relative to distal tip 10, the rolled tip 32 reaches a point where it ceases to be engaged by the device, and it will return to its undeflected configuration (Fig. 5). As the device 58 is being drawn into the lumen 30, however, the lumen 30 will adapt to conformingly hold the device 58 therein and rolled tip 32 will expand radially to accommodate the periphery of the device (Fig. 4). The device 58 will eventually have become fully housed within the

catheter lumen, and the distal tip 10 returns, as discussed above, substantially to its original configuration.

It will be understood that resilient material forming the distal tip 10 prevents the escape of emboli when the embolic protection device 58 is captured. At least a portion of the wall of the distal tip 10 closely encompasses the periphery of the protection device 58 and assumes the shape of the periphery. As a result, emboli are prevented from passing between the periphery of the protection device 58 and the wall of the distal tip 10. Emboli within the protection device 58 are prevented from being released back into the blood vessel. Once the protection device 58 has been received within the catheter lumen, the distal tip 10 resumes substantially the size, shape, and dimensions of its original configuration.

The distal tip 10 is a soft, deformable tip made of an elastic, compliant material. Suitable materials for making the distal tip include thermoplastic polymer and polymer blends or thermoset polymers such as silicone or silicone blends with a low durometer. One such material is a 35/40 D Pebax blend. Any other appropriate compliant materials may, however, be used.

The polymer tip may be filled with radiopaque materials such as barium sulphate, bismuth subcarbonate, tungsten powder, and the like. The tip 10 can be molded or formed using a heated die or in any other such method. Radiofrequency induction heating, electrical resistance heating, conduction heating, or any other method may be used. The preferred dimensions of the formed tip 10 will, of course, depend on the dimensions of the catheter. For example, a range of catheter sizes is from 4.2 F to 6.0 F, with corresponding inner diameters of 0.042 inches and 0.062 inches, respectively. These catheters might have distal tips with rolled distal inner diameter's of 0.025 to 0.050 inches,

respectively. The diameter of the distal tip lumen 30 can be constant or tapered toward the distal end. The tip 10 may be attached to the catheter by any appropriate method such as a unitary design, heating, adhesive bonding, or molding.

It will be understood that this disclosure, in many respects, is only illustrative. Changes may be made in details, particularly in matters of shape, size, material, and arrangement of parts without exceeding the scope of the invention. Accordingly, the scope of the invention is as defined in the language of the appended claims.

What is claimed is:

1. A distal tip for a medical catheter, comprising:

a member having a wall defining a lumen, said member being positionable within a blood vessel such that said member is able to capture a device within said blood vessel, distal of said member, as said device is drawn toward said lumen, said member being adaptable to conformingly hold said device within said lumen.

2. The distal tip according to Claim 1 wherein said member tapers radially inwardly toward a distal end thereof.

3. The distal tip according to Claim 2 wherein said tip is attached to a distal end of a catheter.

4. The distal tip according to Claim 3 wherein said catheter is positioned within a lumen of a human body.

5. The distal tip according to Claim 3 wherein said catheter is positioned within a blood vessel.

6. The distal tip according to Claim 5 wherein said catheter has a lumen and said catheter is advanced along a guidewire disposed within said lumen in said catheter.

7. The distal tip according to Claim 1 wherein said device is an embolic protection device.

8. A catheter having a distal tip, comprising:

a wall defining the distal tip, said tip defining a lumen, the lumen having a distal end, wherein said wall has a curved portion at said distal end curving inwardly toward an axis of said lumen, said lumen having a diameter adaptable to accommodate a device having a diameter.

9. The distal tip according to Claim 8 wherein said distal tip is attached to a distal end of a catheter member.

10. The distal tip according to Claim 9 wherein said catheter is advanced within a blood vessel.

11. The distal tip according to Claim 10 wherein said catheter has a lumen and said catheter is advanced over a guidewire extending therethrough.

12. The distal tip according to Claim 11 wherein said wall has an outer surface, wherein, as said device is drawn into said distal tip, a portion of said device contacts a portion of said outer surface of said curved portion of said wall.

13. The distal tip according to Claim 12 wherein said curved portion accommodates said device into said lumen of said distal tip.

14. The distal tip according to Claim 13 wherein said device is drawn toward said catheter, and wherein said distal tip conforms to said device as it is so drawn.

15. The distal tip according to Claim 14 wherein said device is a protection device.

16. The distal tip according to Claim 15 wherein said distal tip has a diameter that decreases as it progresses towards said curved portion.

17. A catheter comprising:

a distal tip comprising a tubular member having a wall defining a lumen having a periphery wherein said tubular member has a taper from a proximal end towards a rolled distal end wherein at said distal end said wall curves inwardly towards said lumen wherein a device having a greater periphery is urged into said lumen and said lumen adapts to conformingly receive said greater periphery.

18. The distal tip according to Claim 17 wherein said distal tip is attached to a distal end of a catheter.

19. The distal tip according to Claim 18 wherein said catheter is in a lumen of a patient's body.

20. The distal tip according to Claim 19 wherein said device is an embolic protection device.

21. The distal tip according to Claim 20 wherein said distal protection device has particulate matter therein.

22. The distal tip according to Claim 21 wherein said distal tip is attached to a distal end of a catheter.

23. The distal tip according to Claim 22 wherein as said embolic protection device is urged into said distal tip, at least a portion of said particulate matter is prevented from entering said lumen of said patient's body.

24. The distal tip according to Claim 23 wherein as said distal protection device is urged in proximal direction said distal tip conforms to said greater periphery.

25. The distal tip according to Claim 24 wherein as said protection device is urged proximal to said distal tip, said lumen returns substantially to its periphery.

26. The distal tip according to Claim 25 wherein said protection device is received within said catheter body.

27. A medical device comprising: a catheter having at least a single tubular member, said tubular member extending to a distal end; and a distal tubular member connected to and in communication with said catheter distal end wherein said distal tubular member has a wall forming a boundary about a lumen wherein said wall has a thickness that is tapered towards a distal end having a lesser thickness, said distal end of said wall being rolled inwardly towards said lumen forming a rolled tip wherein as said medical device is positioned within a blood vessel said rolled tip is able to receive a protection device into said lumen wherein a corresponding portion of said lumen complies to a periphery of said protection device that is in contact with said corresponding portion.

28. The medical device according to claim 27 wherein said protection device has a periphery wherein said lumen has a periphery prior to receiving said protection device that is less than said periphery of said protection device.

29. The medical device according to Claim 27 wherein said rolled tip is able to contact a portion of a stent at an area of contact and said area of contact will be on an outer surface of said wall.

30. The medical device according to Claim 29 wherein said contact surface is configured such that said distal tip is advanced across said stent.

31. The medical device according to Claim 27 wherein said protection device contains captured emboli and said distal tip is able to comply to said periphery such that emboli are prevented from releasing into said blood vessel.

32. The medical device according to Claim 27 wherein said distal tip has a low durometer.

33. The medical device according to Claim 27 wherein after said protection device is received within said catheter, said distal tip returns substantially to its original configuration.

34. The medical device according to Claim 27 wherein said distal tip comprises a conformable material.

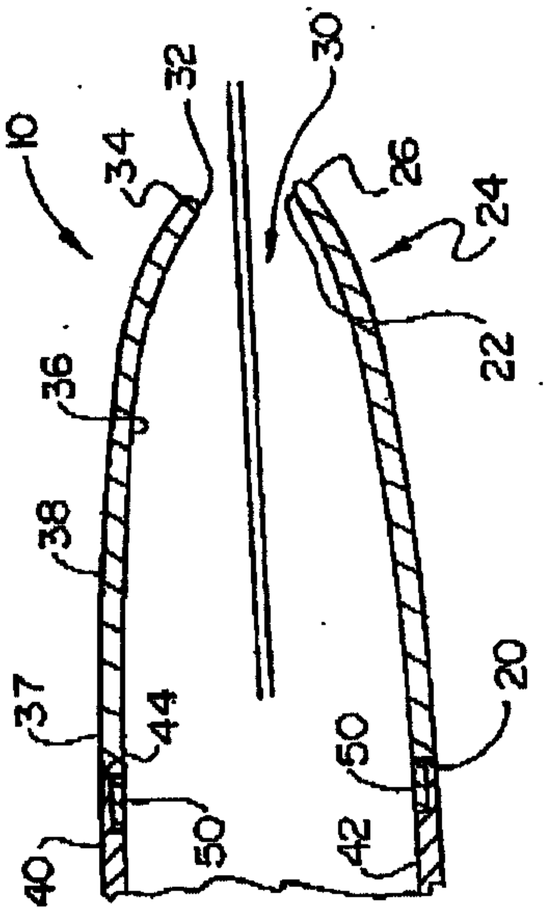

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Fig. 1

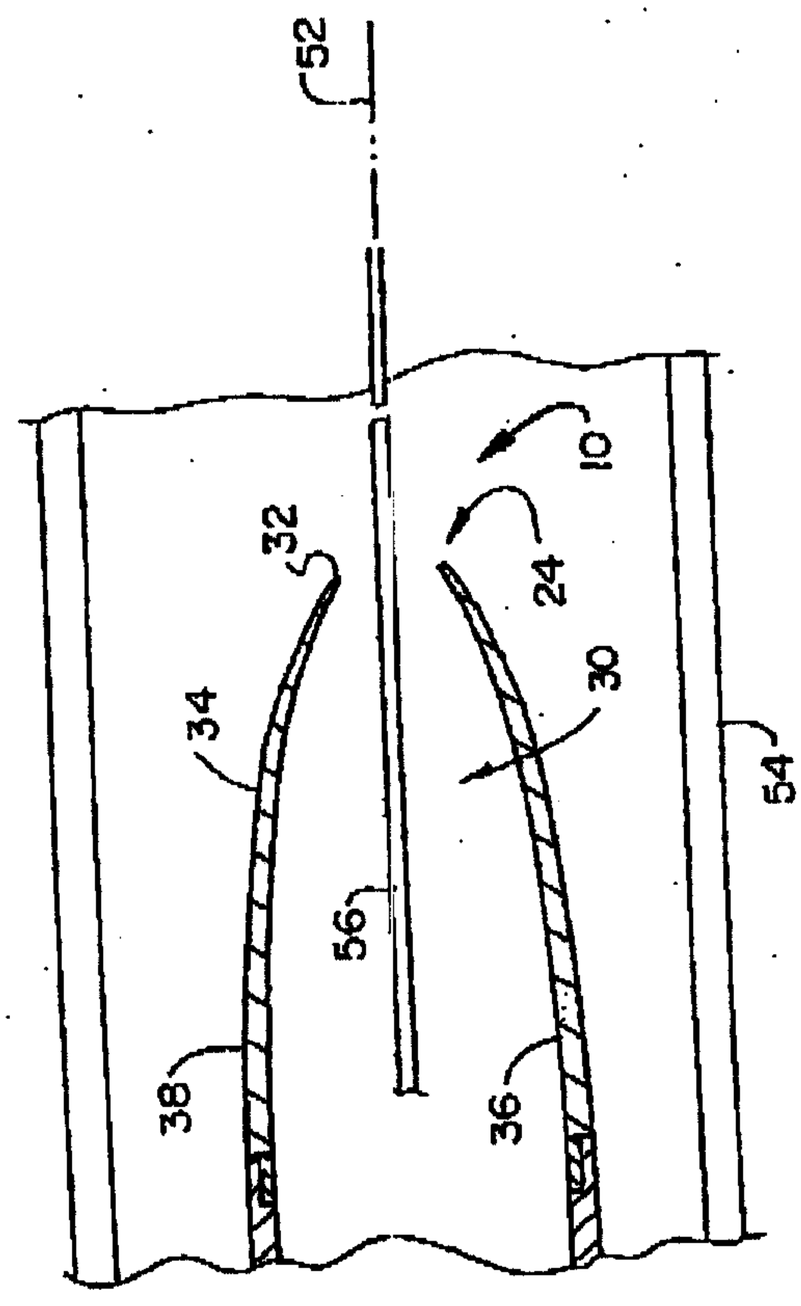
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Fig. 2

Fig. 3

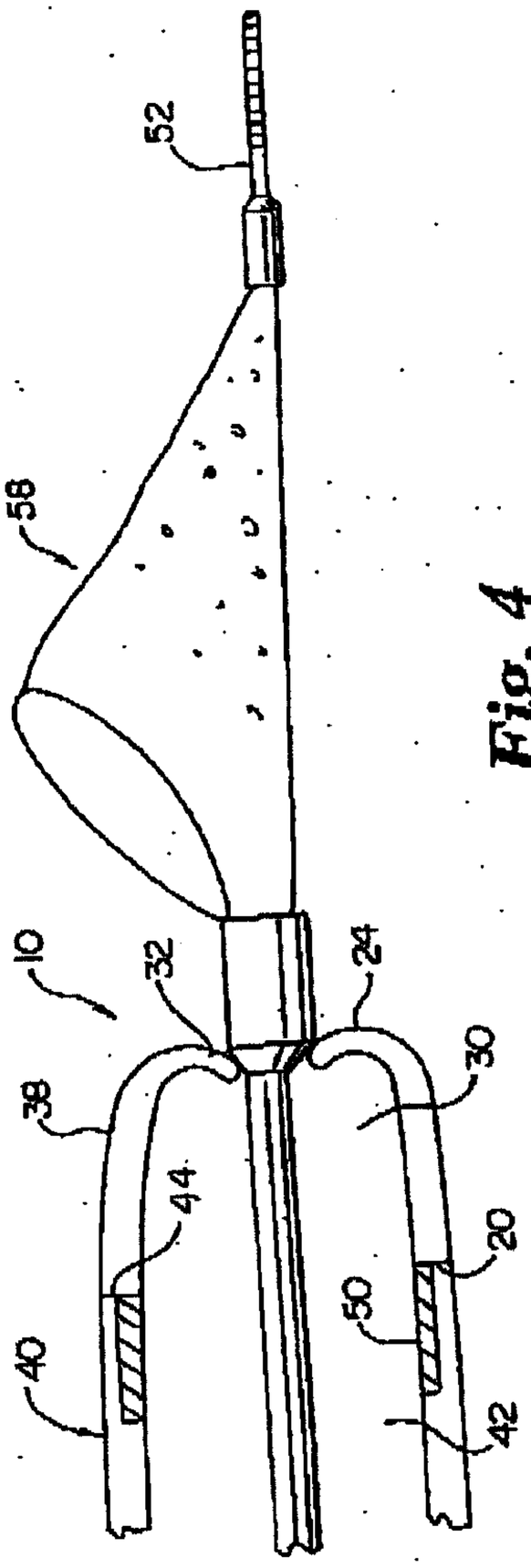
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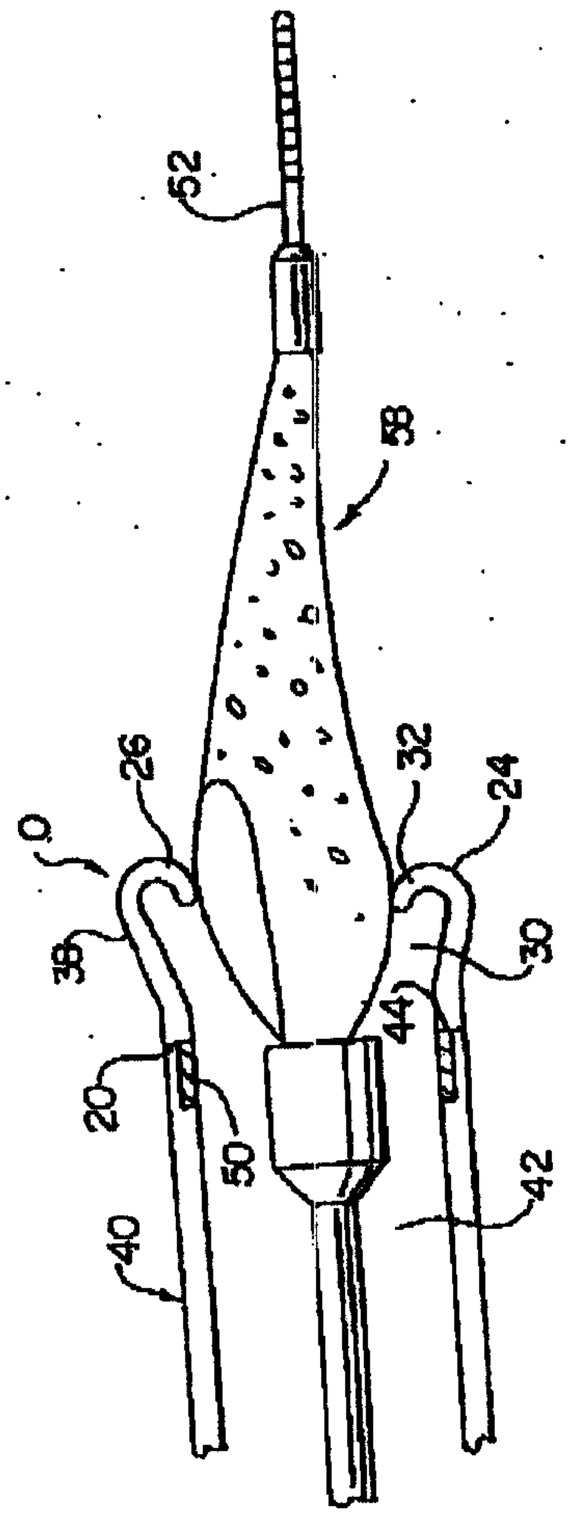
Fig. 4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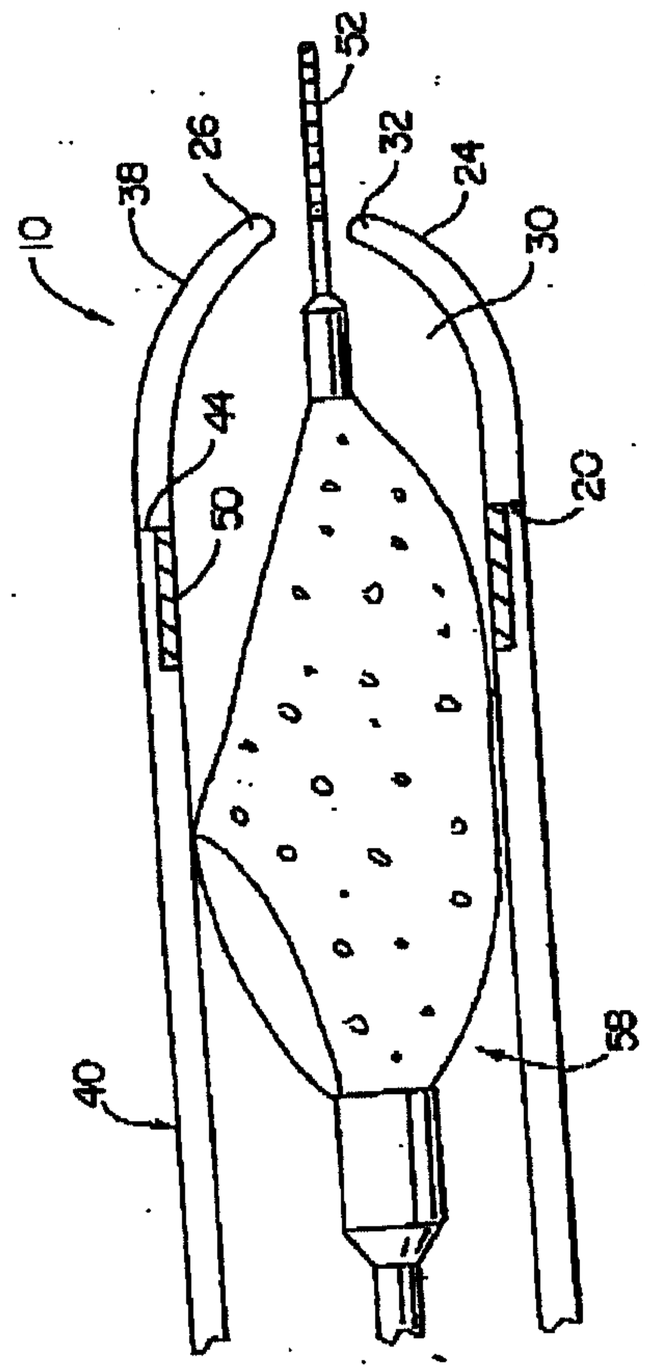
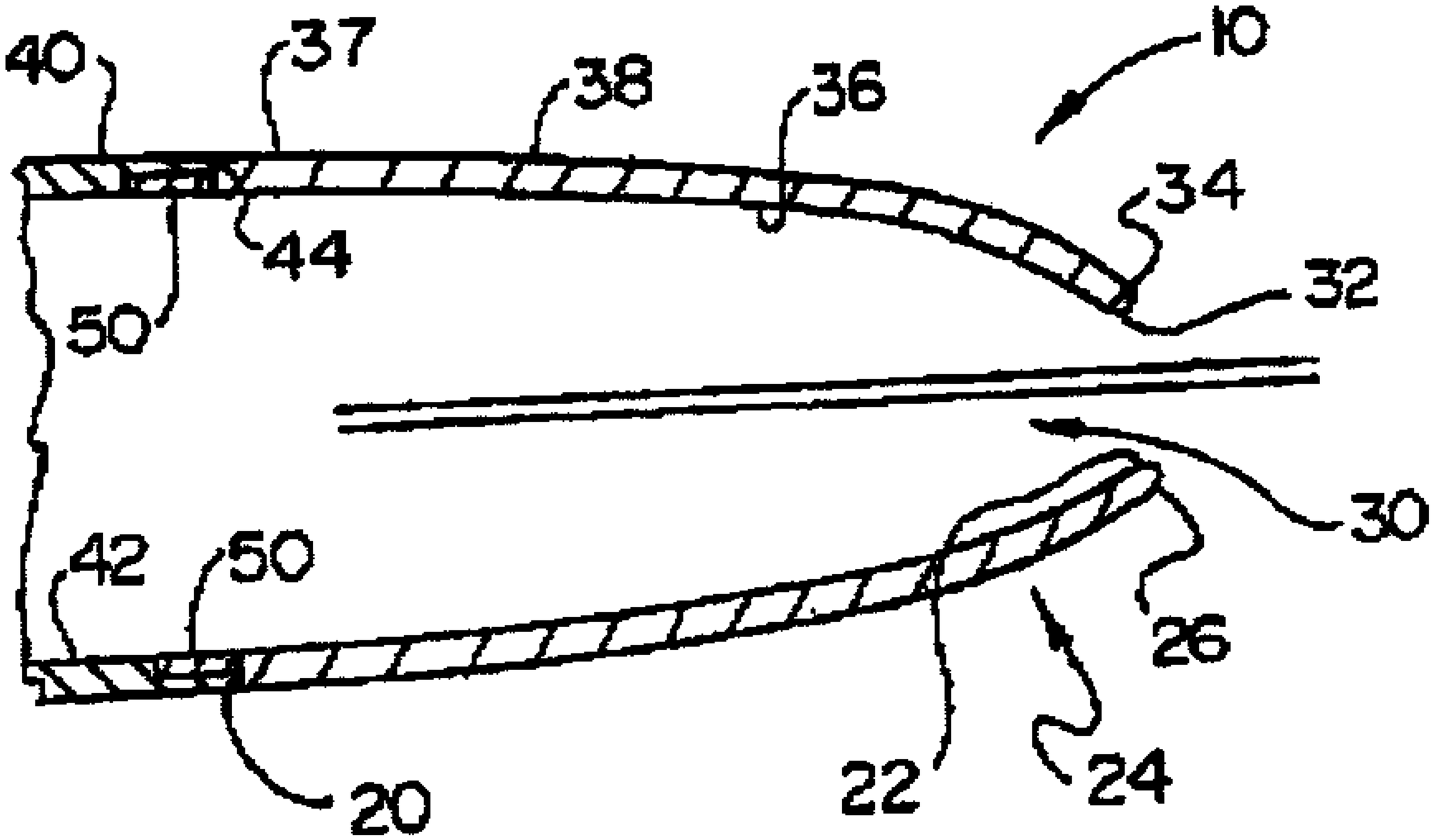


Fig. 5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