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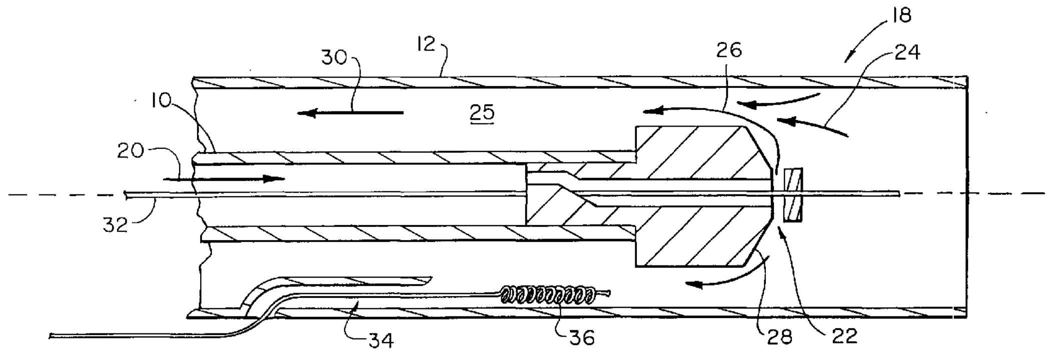
(54) Title: CATHETER SYSTEM



(57) **Abstract:** A hydraulic catheter (10) for removing occlusive material that is powered by a jet (44). The jet (44) of fluid emerges from an aperture and flows along a wall surface. The jet (44) is guided by the wall and the exterior side of the jet interacts with ambient fluid. The catheter may operate alone or inside of a delivery sheath (12).

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CATHETER SYSTEM

CROSS REFERENCE

For the US National Stage Prosecution this application is a CIP of 08/862,277.

FIELD OF THE INVENTION

The present invention is a catheter system for removing occlusive material from the body.

BACKGROUND OF THE INVENTION

Hydraulic catheter devices for the removal of occlusive material from the body are widely known. In general these devices use a small free jet of fluid to remove material from the body. For example the Veltrup device shown in US Patent 4,690,672 ejects a conical free stream of fluid in a retrograde direction. Occlusive material, which comes into contact with the jet, is macerated and forced into a low-pressure discharge lumen.

SUMMARY

In contrast to the prior art the catheter systems, the ablation catheter of the present invention, uses a ring shaped substantially annular jet which flows along the exterior surface of the catheter body. The jet is thin and it is issued next to a barrier surface. As a consequence of the barrier wall, a pressure difference builds across the jet so that it "attaches" to the barrier wall. In operation the fluid jet adheres to the catheter body barrier by generating a low-pressure zone or area between the catheter body and the "interior" surface of the jet. The jet may be ejected in the same direction as the barrier surface or the initial jet direction and barrier surface may diverge. The geometric axis of the jet orifice may direct the jet away from or along the axis of the catheter body.

In one mode of operation the ablation catheter provides a high-energy jet film of fluid surrounding the exterior of the catheter body and this energetic sheet of fluid interacts directly with the occlusive material and emulsifies the occlusive material. In another mode of operation the ablation catheter operates within a sheath and creates a strong suction at the mouth of the sheath to pull occlusive material into the sheath. It is preferred to have the sheath and catheter separately movable so that both modes may be practiced in a single procedure. However separate sheath and fixed sheath versions are taught as well.

Additional structures may be incorporated into the ablation catheter. Distal and proximal balloons are described. The jet may direct fluid flow either proximally or distally and multiple jets may be incorporated in a single device.

The ablation catheter may be delivered via a guidewire in "monorail"; "rapid exchange" or over the wire fashion.

The ablation catheter may be delivered through a sheath and the sheath may include a guide wire passage as well.

BRIEF DESCRIPTION OF THE DRAWINGS

Identical reference numeral indicates identical structure wherein;

Fig 1 shows the catheter system connected to a power injector and collection bag;

Fig. 2 shows a representative ablation catheter in a sheath;

Fig. 3shows a schematic device including an impeller;

Fig. 4 shows device including a remote energy source;

Fig. 5 shows an embodiment of the ablation catheter;

Fig. 6 shows an embodiment of the ablation catheter;

Fig. 7 shows an embodiment of the ablation catheter;

Fig. 8 shows an embodiment of the ablation catheter;

Fig. 9 shows an embodiment of the ablation catheter.:

Fig. 10 shows a cross-section of a jet.

DETAILED DESCRIPTION

Fig. 1 shows the connections to the ablation catheter 10 and sheath 12 assembly. In this figure the sheath is connected to a collection bag 13. In operation fluid is forced by the injector 14 into the high-pressure portion of the system. Saline and CO2 loaded saline are acceptable fluids. Other examples of fluid include contrast agent and therapeutic drug solutions such as lytic drug solution. A guidewire 16 may be inserted through the catheter or the sheath to help position the system in the patient. The distal section 18 is shown in exaggerated scale in Fig. 2.

Fig. 2 shows that the ablation catheter 10 is moveable with respect to the sheath in this embodiment. The high-pressure fluid emerges 26 from the nozzle assembly 22 and "attaches" to the barrier wall 28. The primary stream mixes with and entrains blood and other material 24 from the body and propels the combined flow 30 into the low-pressure lumen 25.

In the construction shown the hypo tube 32 may be used to form a conduit for a guidewire. The sheath 12 may also have a short lumen 34 to carry a guide wire 36.

Fig. 3 shows the ablation catheter used in connection with a mechanical propeller 40, which is turned by a remote motor 42. The jet 44 emerging from the nozzle entrains material from the body. The ablation catheter and impeller are carried in a sheath 12. The sheath may have one or more ports 48 to accept and recirculate occlusive material.

Fig. 4 shows a remote energy source 52 such as an ultrasound generator or laser coupled to a wave guide 54. In operation the fluid passing through the ablation catheter 10 inside the sheath 12 will cool the wave-guide 54. Occlusive material dislodged by the radiating tip 50 energy source will be transported by the ablation catheter 10 and sheath to a location outside the body.

Fig. 5 shows a construction of an ablation catheter that is "unitary" and ports or slots 60 are cut in the catheter tip to allow fluid to emerge. In this example a ring like step 62 separates the slot 60 from the inclined barrier surface 64. It has been found that this step can encourage the attachment of the jet to the barrier surface 64 and promote turning of the jet 68. In general it is desirable to have several slots typified by hole 60 to direct the flow. It has been found that it is preferred to have as continuous a sheet of fluid as possible although the wall attachment effects occur even with individual jets depending on geometry. Although inclined surfaces and cylindrical surfaces for the barrier wall as easy to fabricate and operable it may be preferable to use more complex surfaces including the parabolic and spherical surfaces depicted in the figure for some applications. The unitary structure can be fabricated enitly of a metal such as NITINOL and the device can act as a guide wire. If used with a sheath 12 a short lumen 34 can be used to deliver a guidewire 36.

Fig. 6 shows a multiple nozzle assembly that can be used inside or outside a sheath 12 having a first jet annulus 70 and one or more "booster" jets 72. In this device the high-pressure fluid from the injector 14 enters the nozzle though the hypo tube 74where it enters a plenum 76. The fluid feeds the annular gap 70 generating primary streams depicted as jet 80 and jet 82. Booster jet 84 is directed at an acute angle in the proximal direction of about sixty degrees and the jet 84 attaches to wall 88 and the several jets operate together to discharge material into the low pressure lumen 25.

Fig. 7 is a schematic view showing the flow path for an ablation catheter that has a concave barrier surface 70. The free space flow direction of the jet issuing from the nozzle is shown by dotted line 72. In this instance the jet is one hundred and eighty degrees from the axis of the catheter body and is therefore parallel to it. The inclined concave surface meets the jet aperture at an angle shown by dotted line 74. In this figure the fat arrow 76 is a somewhat exaggerated direction of flow for the augmented stream. This concave surface 70 has several features of the step seen ion Fig. 5 and also shows the ability of the combined stream to follow a rapidly changing barrier wall shape.

Fig. 8 is a schematic diagram that shows that the barrier surface need not be rigid. In this schematic an elastic spherical balloon 80 forms the barrier surface. In this example the free jet direction 72 and the tangent to the barrier surface at the location of the connection between the barrier and the aperture are essentially the same.

Fig. 9 shows the barrier surface as a set of stepped cones. The free stream direction of the jets 72 and the angle that the conical surfaces meet the aperture depicted by tangent 74 are essentially the same.

The wall attachment effects require that the jet emerge into a fluid. However during testing it is common to squirt fluid into the air. The direction of fluid flow in air is the free stream direction of flow.

These figures taken together show that the geometric direction of the "jet" may form an angle with respect to the catheter axis of from approximately 90 degrees (or right angle to the axis) to 180 degrees in the examples (or parallel to the axis). A broad range of angles can be used for the free stream direction of the jet. Also the barrier surface may form an angle with the geometric axis of the initial jet direction of between about zero degrees and sixty degrees or more in the figures. The inclusion of steps 62 provides an example of a wall barrier to jet aperture angle of 180 degrees. In use the pressure difference across the jet causes the fluid stream to run next to the barrier surface and this allows the barrier surface to turn through a greater or lesser degree of turning. Even at small degrees of turning the barrier surface minimizes energy loss in the jet and decreases the amount of blood lost during the procedure.

Fig. 10 is a cross section or slice out of a device that shows the operation of the jet in more detail. In the figure the aperture or slit 100 has a geometric direction shown as dotted line 102. When operated in air the fluid will generally follow this free stream direction or path. The barrier wall 104 is at an angle to the free stream direction shown in the figure. In practice this angle can vary from about 0 degrees up to about 60 degrees. Small steps of up to 90 degrees can be used to promote adhesion of the jet. However typically 45 degrees is a usable value for the inclination of the jet to the barrier wall.

When the jet first issues from the aperture 100 it has a small cross section area and a very high stream velocity. As this jet 99 begins to exchange momentum with the surrounding fluid s the jet become broader but move at lower speed this is depicted as jet cross section 98. This momentum exchange process is minimized on the barrier side of the jet near the barrier wall 104. In fact a recirculation bubble 106 occurs in most instances although it is very difficult to detect directly. The arrow loop depicts the bubble in the figure. The effect takes place within of a variety of wall shapes. The free jet direction 102 may be inclined with respect to the catheter body from an angle of more than ninety degrees to about one hundred and eighty degrees.

What is claimed:

1. An ablation catheter having:

a high-pressure lumen;

one or more opening apertures connecting the high pressure lumen with the exterior of the catheter;

a barrier wall located near the opening;

whereby a pressure difference occurs across the jet to cause the jet to attached to the barrier wall.

2. The ablation catheter of claim 1 wherein:

said aperture creates a free stream direction for the emerging fluid having a first direction;

said barrier wall meet said aperture at a first angle with respect to said first direction;

said angle lies between about 0 to 60 degrees.

3. The ablation catheter of claim 2 having:

a second direction defined as the axis of said catheter body;

said barrier wall forming an angle with respect to said body of zero to 90 degrees.

4. The ablation catheter of claim 1 further including:

a guide wire lumen extending at least part of the length of said catheter.

5 An occlusion removal system comprising:

an ablation catheter having a fluid jet generating a free stream retrograde flow;

a sheath surrounding the ablation catheter;

whereby pressures difference develops in the sheath to entrain material into the distal opening of the sheath.

6. The system of claim 5 further including a guide wire lumen in said sheath.

7. The ablation catheter of claim 1 wherein said barrier wall is a substantially spherical shape.

8. The ablation catheter of claim 1 wherein said barrier wall is a cylinder aligned parallel with a catheter body axis.

9. The ablation catheter of claim 1 wherein said barrier wall is a substantially parabolic shape.

10. The ablation catheter of claim 8 wherein said barrier wall is an inflatable balloon shape.

11. A catheter comprising:

a catheter body having a distal end and a proximal end and having an exterior surface;

a high-pressure lumen within aid catheter body supplying fluid under pressure to said distal end;

an opening in said catheter body connecting said high pressure lumen with said exterior of said catheter body, thereby forming a jet of fluid;

said jet of fluid having a first interior side located proximate said exterior of said catheter body, and having a second exterior side exposed to ambient fluid.

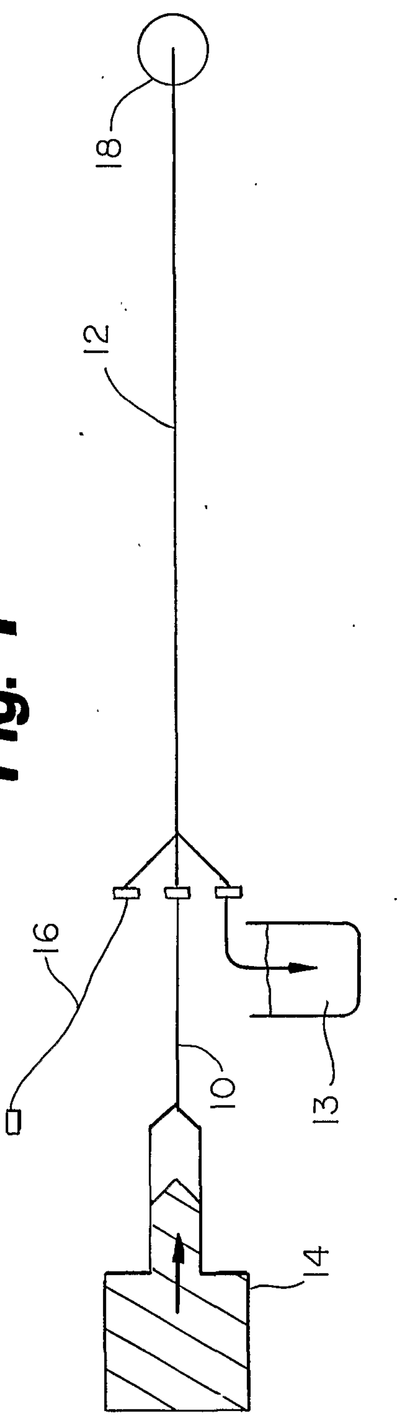


Fig. 1

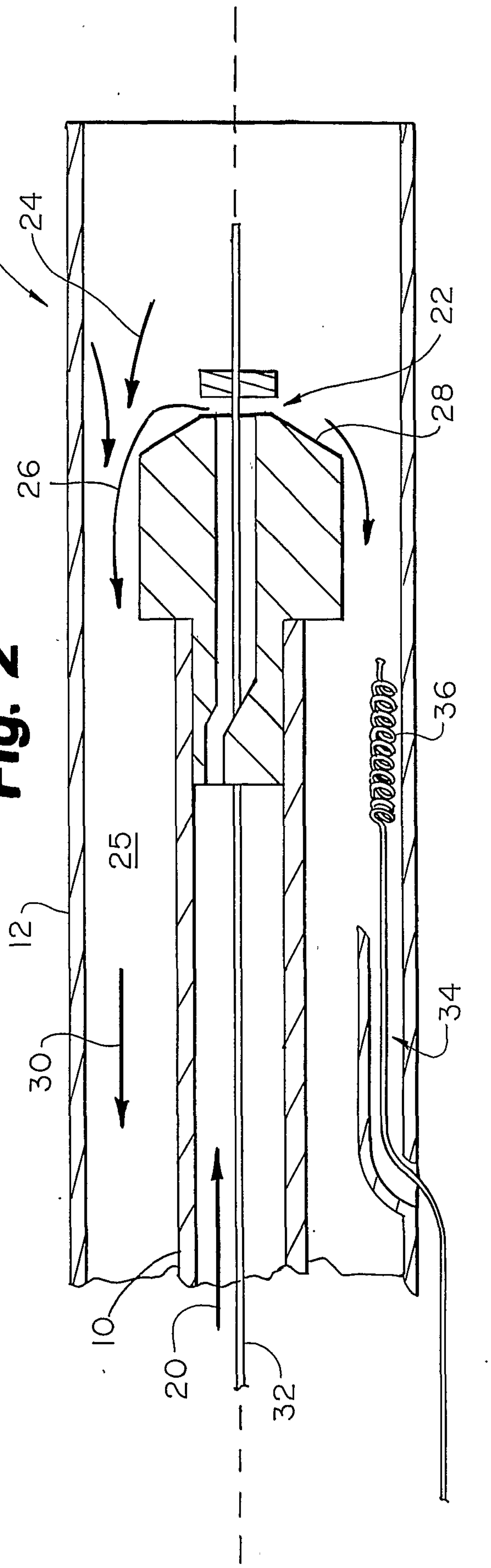


Fig. 2

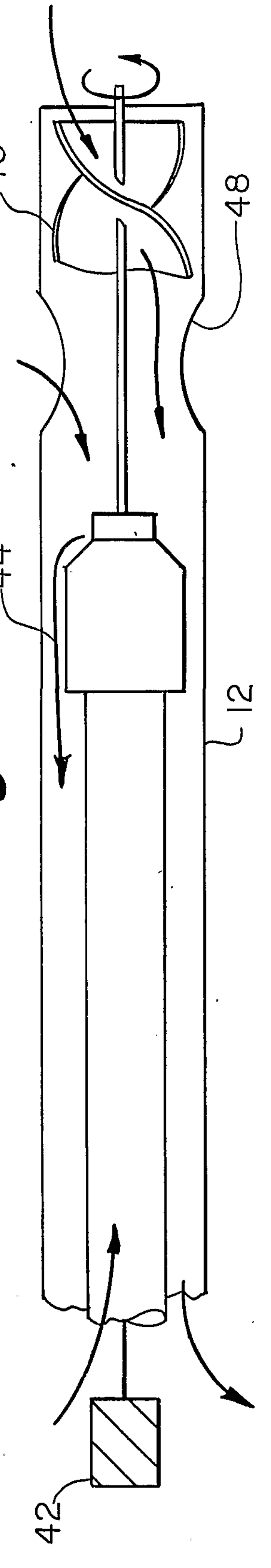


Fig. 3

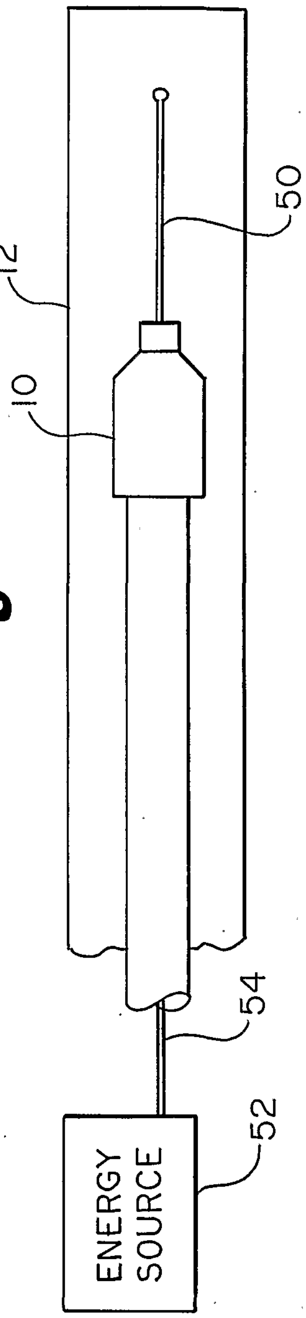
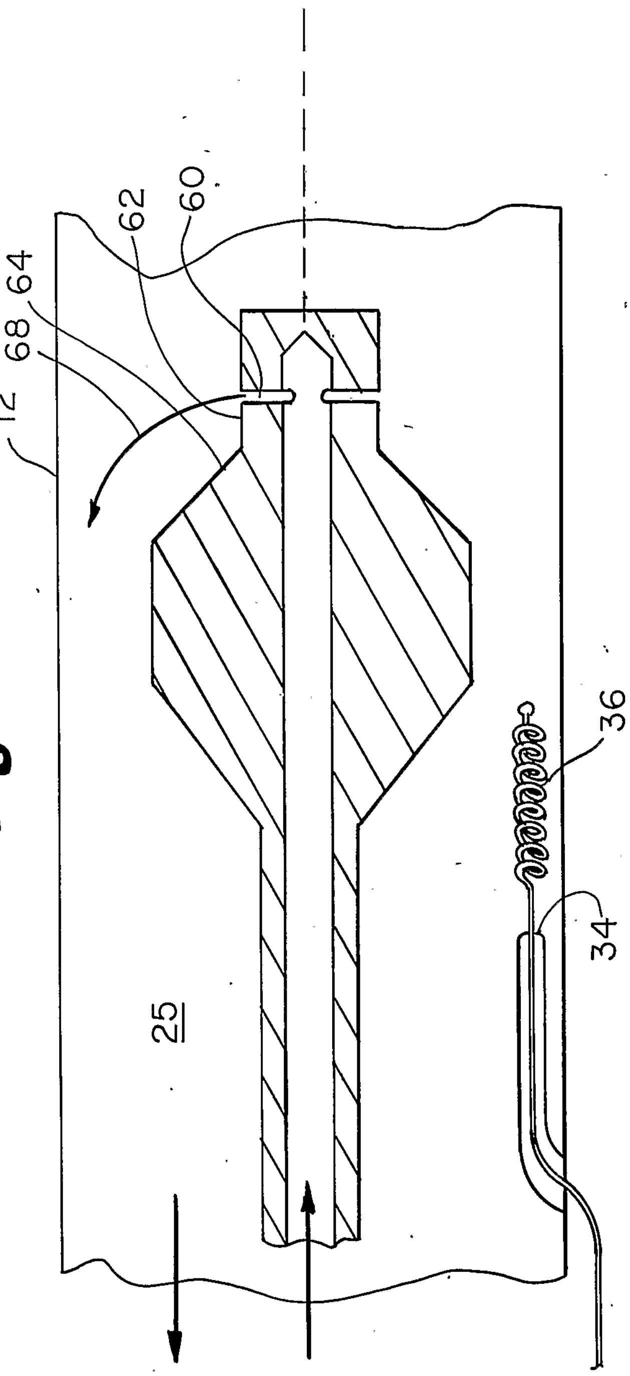


Fig. 4

Fig. 5



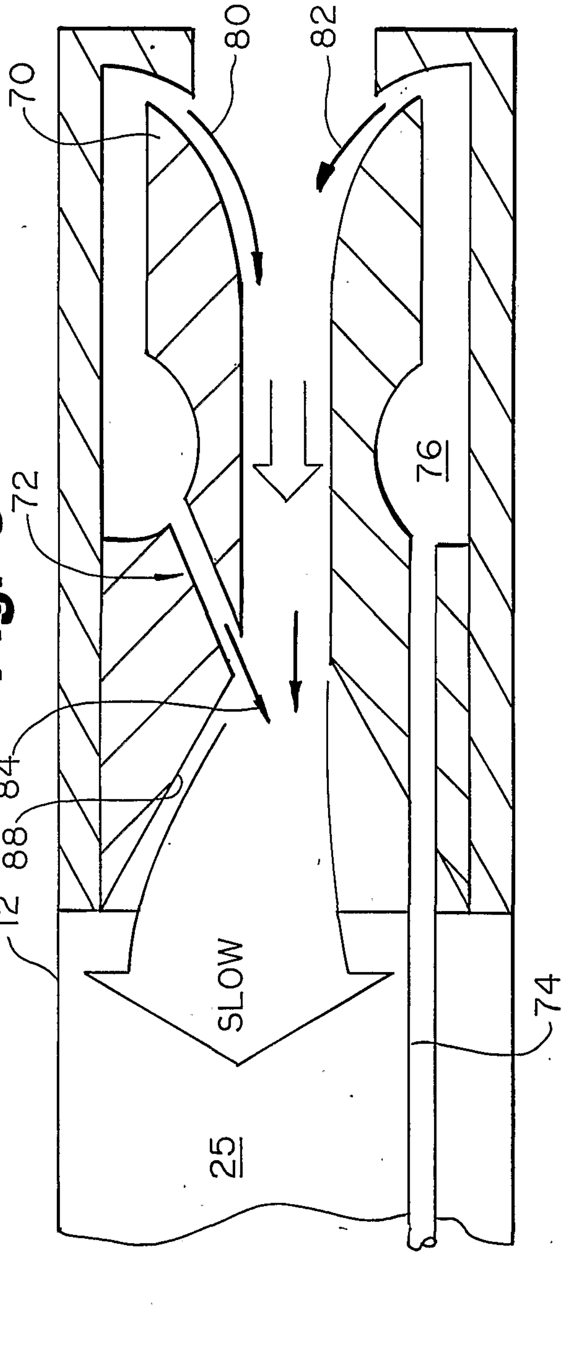


Fig. 6

Fig. 7

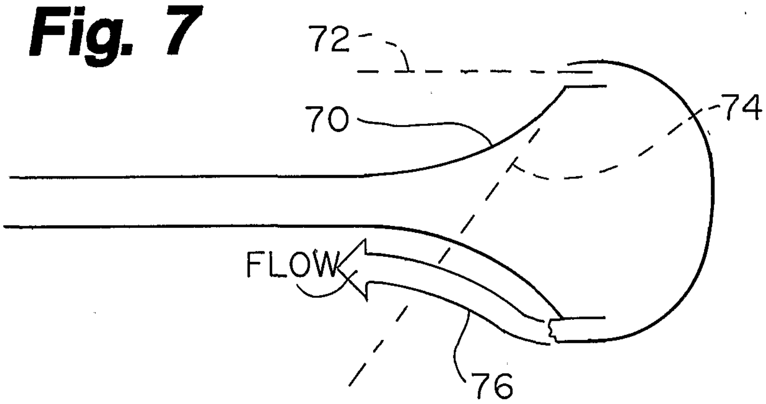


Fig. 8

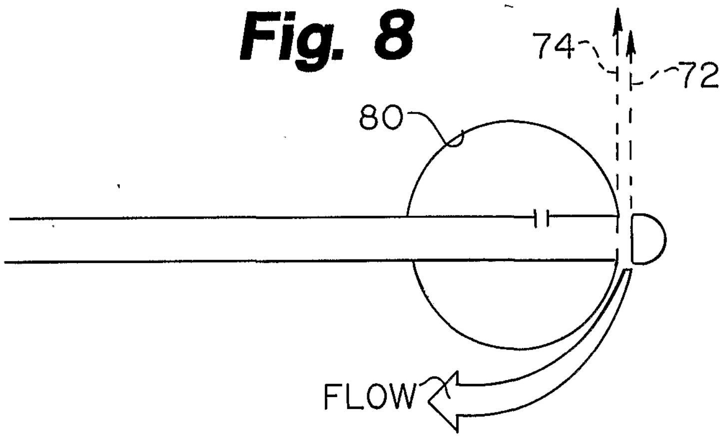


Fig. 9

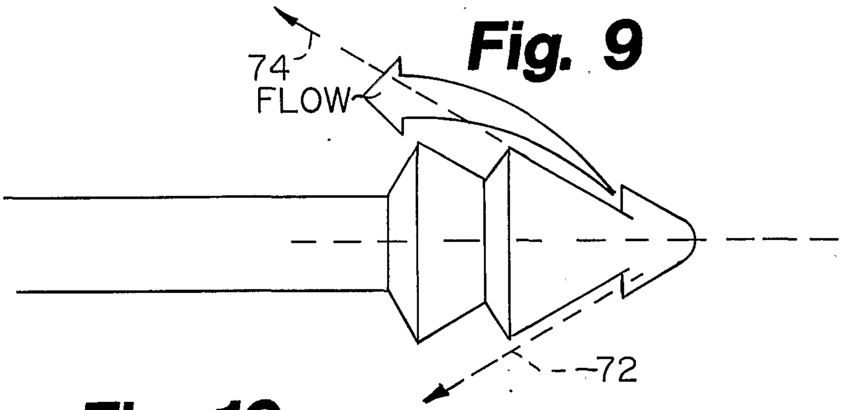
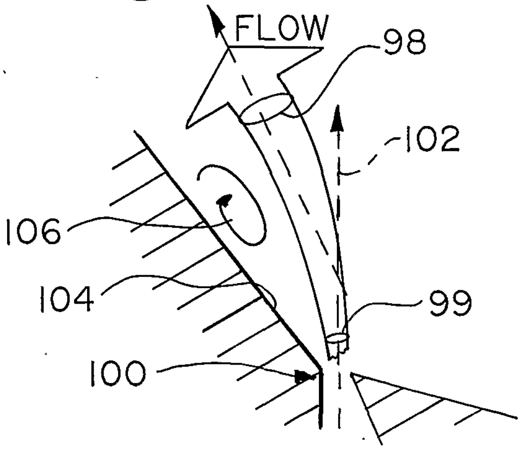


Fig. 10



SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/26770

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61M 1/00
US CL : 604/27
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/19-22, 27, 35

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,273,526 A (DANCE et al.) 28 December 1993, see entire patent.	1-11

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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27 DECEMBER 2000	12 JAN 2001

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