

[54] **EMBOLECTOMY CATHETER**
[72] Inventor: Charles H. Klieman, Brooklyn, N.Y.
[73] Assignee: United States Catheter & Instrument Corporation, Glens Falls, N.Y.
[22] Filed: Dec. 2, 1969
[21] Appl. No.: 881,363

[52] U.S. Cl. 128/348, 128/356
[51] Int. Cl. A61m 25/00, A61b 17/22
[58] Field of Search 128/348-351, 344,
128/303, 325, 246, DIG. 9, 2, 356, 328

[56] **References Cited**

UNITED STATES PATENTS

2,701,559 2/1955 Cooper 128/2
3,467,101 9/1969 Fogarty et al. 128/348
2,024,982 12/1935 Scott 128/349 X

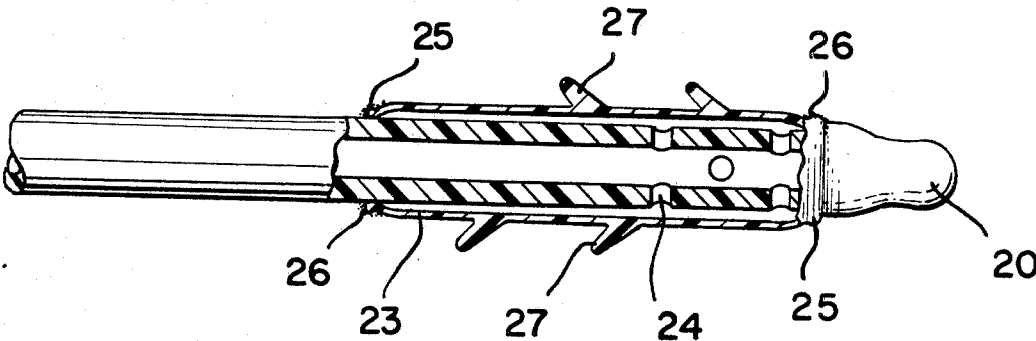
2,856,934 10/1958 Petillo 128/349 X
2,688,329 9/1954 Wallace 128/349
2,788,787 4/1957 Trace 128/303
3,308,819 3/1967 Arp 128/215
3,416,531 12/1968 Edwards 128/348

Primary Examiner—Dalton L. Truluck
Attorney—W. Saxton Seward

[57] **ABSTRACT**

Apparatus for extracting emboli comprising a cannula, preferably guidable, adapted to be projected through a body passage (e.g., vein or artery) to a point adjacent the embolus to be removed, together with a catheter adapted to be passed through the cannula and having a distal end provided with an inflatable balloon the surface of which has rearwardly angled protrusions designed to engage an embolus into which the catheter end has been projected and to convey the captured embolus into the cannula as the catheter is withdrawn therein.

7 Claims, 7 Drawing Figures



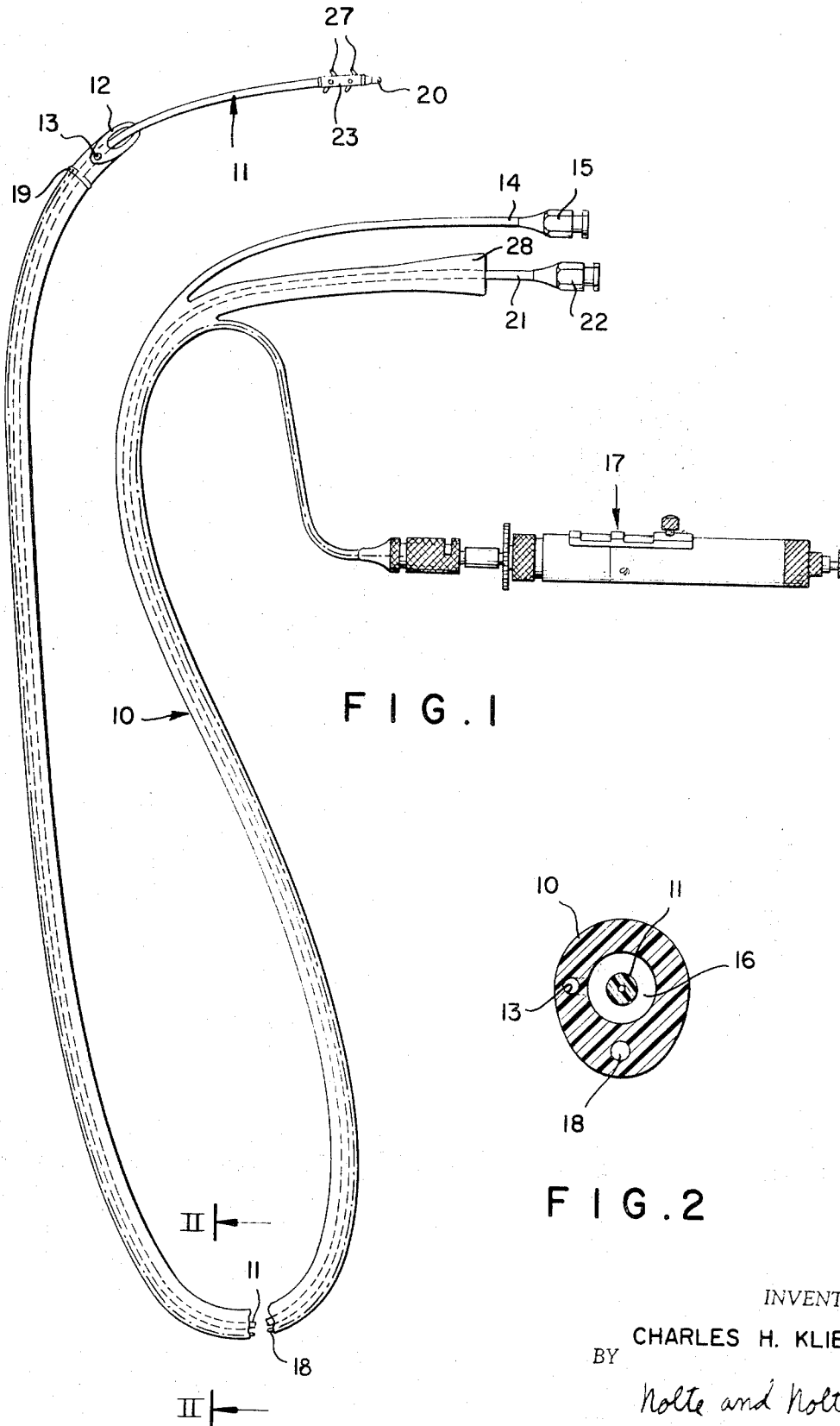


FIG. 1

FIG. 2

INVENTOR.
 CHARLES H. KLIEMAN
 BY
Nolte and Nolte
 ATTORNEYS

FIG. 3

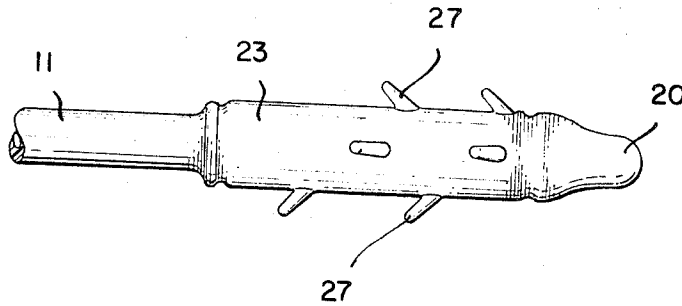


FIG. 4

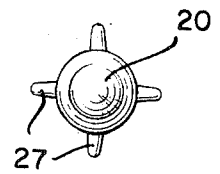


FIG. 5

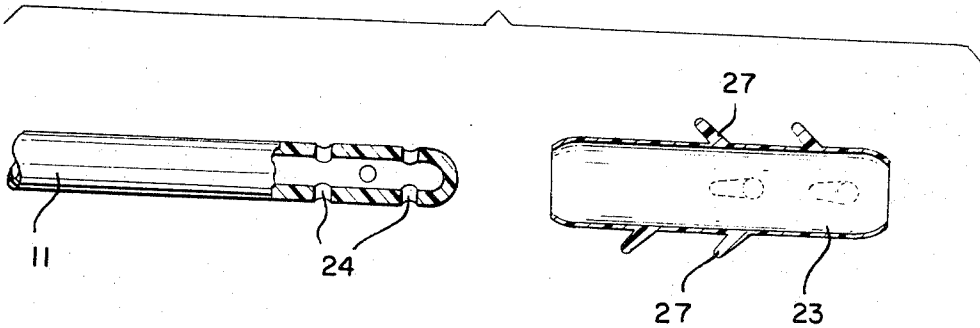


FIG. 6

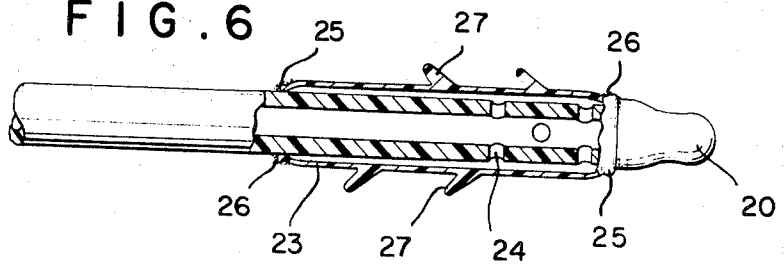
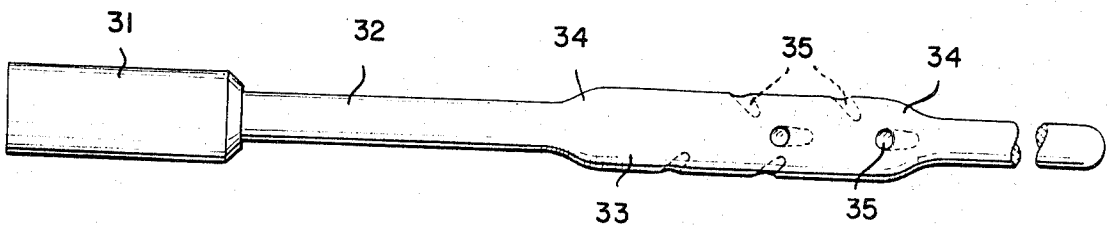


FIG. 7



INVENTOR.
CHARLES H. KLIEMAN
BY
Holte and Holte
ATTORNEYS

EMBOLECTOMY CATHETER

BACKGROUND OF THE INVENTION

A definite need exists for a catheter unit to remove pulmonary emboli. A pulmonary embolus is a blood clot that has formed in some area of the body and traveled via the venous system into the pulmonary arteries. The site of origin of these emboli is usually the veins of the leg, secondary to conditions such as thrombophlebitis. If a massive pulmonary embolus occurs, the mortality rate is high. The only method available at this time to remove these clots is by a direct surgical attack on the pulmonary artery. Even then the mortality rate is very high. The present catheter unit's purpose is to avoid the need for surgery and permit the emboli to be removed via a peripheral vein such as the femoral vein. Other uses have been developed for one or both parts of the catheter unit to be described. Each use will be described in detail.

A practical embodiment of the invention is shown in the accompanying drawing wherein:

FIG. 1 represents an elevation of the outer guided cannula with the extraction catheter inserted therethrough, parts being broken away;

FIG. 2 represents a cross section on the line II—II of FIG. 1;

FIG. 3 represents an elevation of the distal tip of the extraction catheter on an enlarged scale;

FIG. 4 represents an end view of the tip shown in FIG. 3;

FIG. 5 represents detailed axial sections of the catheter, adjacent its distal tip, and of the balloon prior to assembly thereof;

FIG. 6 represents the same parts as in FIG. 5, assembled; and

FIG. 7 represents an elevation of a mandrel on which the balloon may conveniently be formed.

Referring to the drawings, the apparatus is shown as comprising two parts, the outer guided cannula 10 and the inner catheter 11, constituting the emboli-extracting instrument.

The outer cannula 10, which may be 80 cm. to 100 cm. in length, is preferably 20 F. in diameter with a substantially circular lumen having a diameter on the order of 0.164 inch, its distal end 12 being opened at an angle to provide an actual opening larger than the lumen. The cannula 10 is formed with a main lumen 16 and a small second lumen 13, open at the distal end (e.g., in the short end of the bevel) and provided at its tubular proximal end 14 with a fitting 15, to receive a syringe tip for the injection of dye, for instance. The cannula 10 is flared proximally, as indicated at 28, to permit insertion of the catheter 11, as described below; it is also provided with a deflecting device comprising the operating handle 17 and a fine wire 18 secured at its distal end 19 near the distal end 12 of the cannula, by which means said cannula end can be deflected, in a known manner, and guided to desired locations. The handle 17 may be of the type shown in Muller U.S. Pat. No. 3,425,740, or an adaptation thereof. The material of the cannula 10 is suitably a radiopaque polyvinyl chloride or equivalent nonreactive, nontoxic and atraumatic material, with or without wire reinforcement.

The inner catheter 11, 20 cm. to 25 cm. longer than the cannula 10 may be 3 F. to 8 F. in diameter, radiopaque and of woven Dacron or the like. Its distal tip 20 is soft, flexible and closed, and its proximal end 21 is provided with a fitting 22 to receive tip of a syringe for a purpose described below. The catheter 11 has an inflatable balloon 23 of latex, vinyl or other suitable elastomeric material mounted adjacent its distal tip, the balloon being constituted by a substantially cylindrical sleeve long enough to cover the openings 24 normally provided near the tip of such a catheter, the ends of the sleeve being tied by threads 25 and tightly secured to the surface of the catheter by said threads and by an application of a suitable adhesive 26 over the threads and adjacent edges of the sleeve.

The balloon is provided with a plurality of integrally formed "barbs" or protrusions 27, each approximately 1 mm. in length, slanted away from the tip of the catheter at angles of 30° to 60°, for instance (45° being shown), and distributed

around the balloon surface at intervals preferably no greater than 90° with respect to the catheter axis. The diameter of the balloon portion, including protrusions 27, should be not appreciably greater than the inside diameter of the cannula (e.g., less than 0.164 inch) with the balloon collapsed (not inflated), to enable said portion to be passed through the cannula, as described below, without undue frictional resistance.

In using the apparatus for pulmonary embolectomy, the emboli-extracting catheter 11 is placed within the outer cannula 10, the unit is introduced into the femoral vein, and under observation with an image intensifier, is guided up through the vena cava, through the right side of the heart and out into the pulmonary artery. Dye is then injected to determine the exact location of the embolus, so that the distal end of the cannula 10 may be placed close to it. The inner catheter 11 is pushed through and past the clot, (e.g., to a position as shown in FIG. 1 with respect to the cannula 10) and then pulled back, the protrusions 27 engaging the clot and ensuring its capture and withdrawal into the cannula through the enlarged opening in the end 12. If necessary, due to the size of the vein and/or clot, the balloon 23 may be inflated by means of a syringe engaged in the fitting 22, the vinyl balloon having sufficient elasticity to permit an appreciable increase in its effective diameter. Following the first withdrawal of the catheter into the cannula, dye is again injected to determine if all the clot has been removed, and repeated projections and retractions of the catheter can be made until the clot removal is completed. The slanting arrangement of the protrusions 27 ensures that they will engage the clot only for withdrawal, emerging from the cannula relatively "clean" for each repeated pass, if more than one pass is needed. When the clot appears to have been completely captured, the entire unit is removed.

It has been found that, in many instances, the presently used Fogarty catheter is not fully effective to remove iliofemoral venous or arterial emboli. The inner emboli-extracting catheter 11 can be used (without the cannula 10) for this purpose. Its advantages reside in the soft flexible tip, the vinyl balloon with slanted protrusions, and its ability to remove clots without necessarily having to inflate the balloon in the vessel. In such an operation the catheter is introduced distally into the femoral artery or vein and advanced past the embolus, the soft flexible tip ensuring that the vessel wall will not be damaged. After the balloon has been pushed past the clot, it is withdrawn, the protrusions 27 engaging the clot and removing it. If necessary, the balloon may be inflated to the desired extent to ensure engagement with and removal of the clot. Repeated passes may be made into the femoral, deep femoral, popliteal and iliac vessels to completely remove the clot or clots. The protrusions on the balloon are rounded and sufficiently flexible to avoid damage to the vessel but are firm enough to hold onto the clot. When using the catheter 11 without the cannula 10 it is particularly convenient and desirable for the catheter to be calibrated at suitable intervals such as every 10 cm.

Instances have been reported of occlusion of the renal artery by emboli, and the only presently known procedure for saving the affected kidney is operating on the patient to remove the clot. The cannula and catheter described herein can be used to remove such clots, thus avoiding the need for surgery. In this situation, the assembled unit is passed up the femoral artery to the level of the renal artery, as located by the injection of dye. The slant-opened distal tip 21 of the cannula is approximated to the opening of the renal artery and the inner catheter 11 is then projected into the renal artery to pass, engage and remove the clot or clots as described above. The clot or clots captured with the cannula are then removed as the cannula is withdrawn.

A convenient and economical means for making the balloon 23 is illustrated in FIG. 7, where the metal (e.g., brass) mandrel 30 is shown as having a handle 31, a shank 32 and a cylindrical enlarged portion 33 tapering smoothly at both ends to the diameter of the handle, as indicated at 34. A plurality of slanting tapering holes 35 are drilled at suitable points, cor-

responding to the desired number and distribution of the projections 27. The mandrel is used by dipping in a bath of elastomeric material, maintained sufficiently liquid to flow into the holes 35, the material depositing on the mandrel to the desired thickness. After removal from the bath, the deposited material is cured in an appropriate manner, the sleeve with "barbs" on its inner surface is turned inside out, and the ends trimmed to leave a balloon as shown at the right of FIG. 5. The inside diameter of the cylindrical portion of the balloon may conveniently be slightly greater than the outside diameter of the catheter, as indicated in FIG. 6, the actual difference being on the order of 0.010 to 0.020 inch.

As used herein, "distal" refers to the leading end or direction of advancement into the body and "proximal" refers to the end or direction opposite to said distal end or direction.

What is claimed is:

1. An embolectomy catheter comprising an elongated tubular body having a closed soft flexible distal tip, at least one perforation through the wall of said tubular body adjacent said tip, inflatable sleeve of elastomeric material covering said perforation and sealed to the surface of said body distally and proximally of said perforation, and a plurality of protrusions of the same material integrally formed on said sleeve at a plurality of circumferential points, projecting laterally therefrom and slanted away from said distal tip, whereby when said tip is inserted within a blood vessel past an embolus, said slanted

protrusions will engage said embolus and upon retraction of said catheter will ensure withdrawal of said embolus from the blood vessel.

2. A catheter according to claim 1 which includes a fitting on the proximal end of said body adapted to receive a syringe tip.

3. A catheter according to claim 1 in which the catheter is of a woven plastic material having dimensional stability and being at least partially radiopaque.

4. A catheter according to claim 1, in which the sleeve is sealed to the body by a circumferential tie covered by adhesive.

5. In combination, a catheter according to claim 1 and an outer cannula having at least one lumen open at both ends, the diameter of said lumen being substantially as great as the diameter of a circle passing through the outer ends of said protrusions, the length of said cannula being less than the length of the catheter, and said catheter being slidably received within in said cannula.

6. The combination of claim 5 in which the distal end of the cannula has a slanted opening, the area of which is larger than the cross-sectional area of the cannula lumen.

7. The combination of claim 5 in which the cannula is a radiopaque vinyl plastic and the catheter is at least partially radiopaque.

* * * * *

30

35

40

45

50

55

60

65

70

75