

Dec. 2, 1969

S. SOBEL ET AL

3,481,338

GAS ENDARTERECTOMY NEEDLE

Filed April 26, 1967

3 Sheets-Sheet 1

FIG. 1

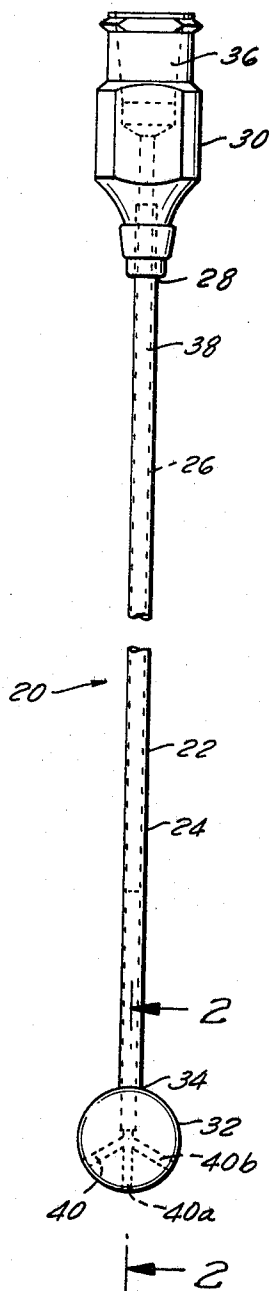


FIG. 2

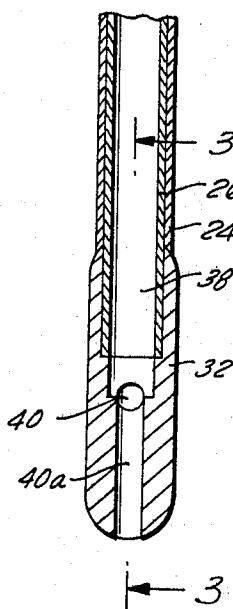


FIG. 3

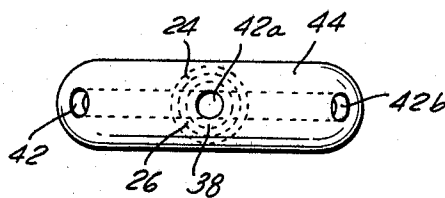
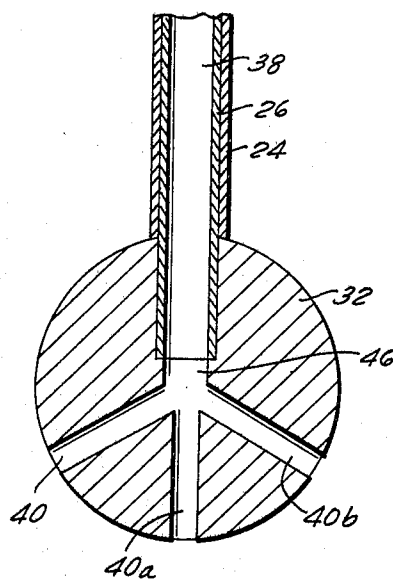


FIG. 4

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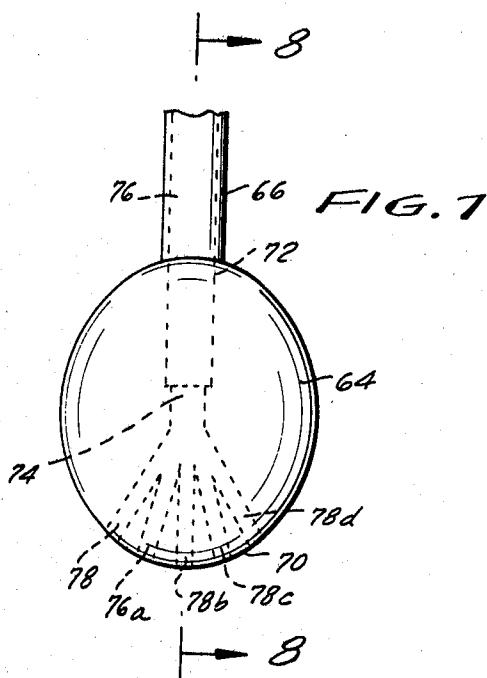
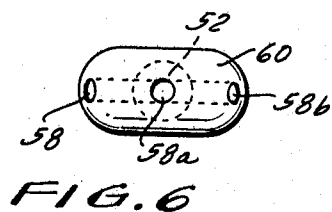
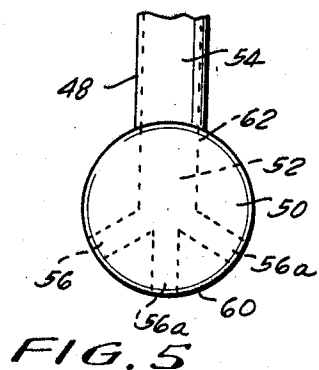
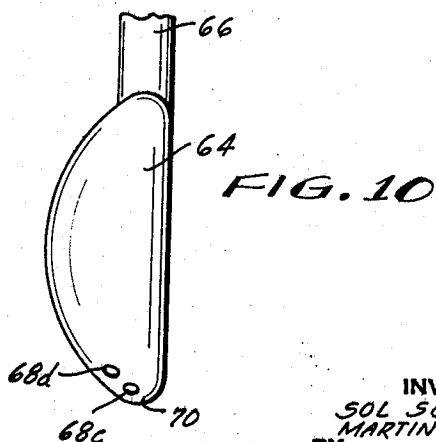
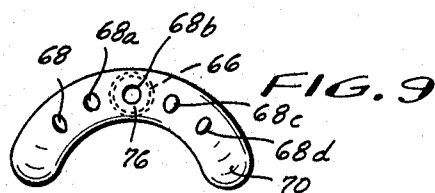
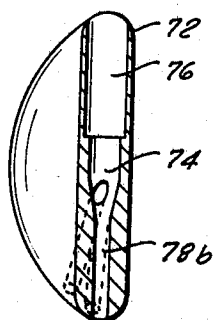


FIG. 8



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FIG. 11

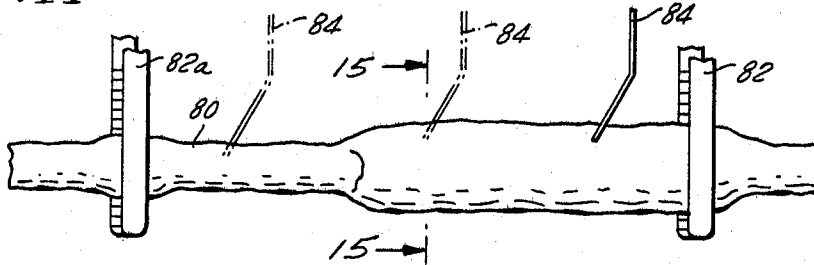


FIG. 12

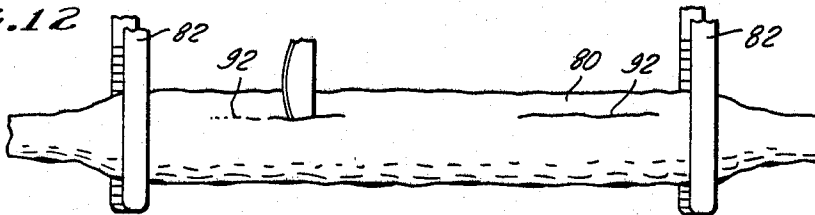


FIG. 13

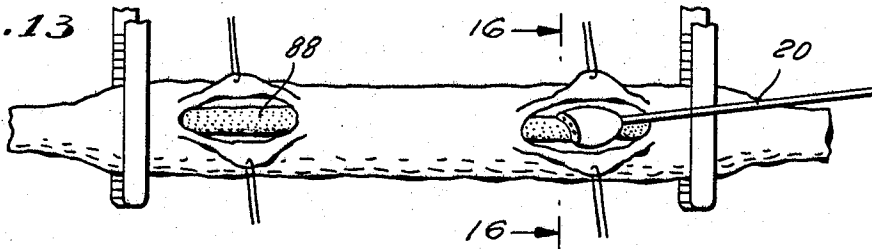


FIG. 14

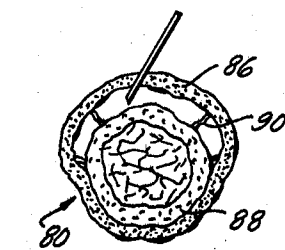
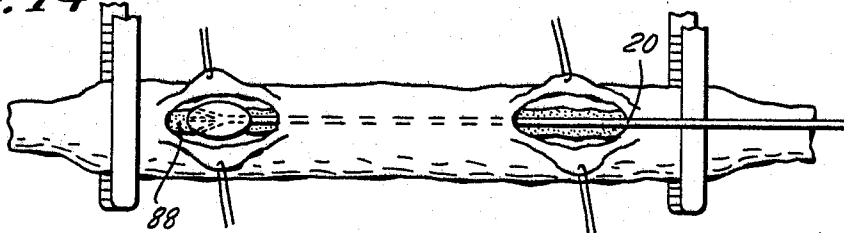


FIG. 15

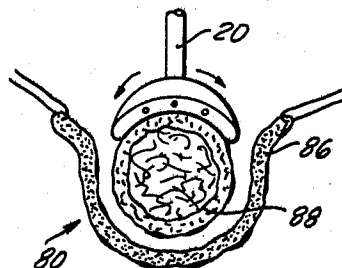


FIG. 16

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## GAS ENDARTERECTOMY NEEDLE

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U.S. Cl. 128—303

7 Claims

### ABSTRACT OF THE DISCLOSURE

A needle for use in gas endarterectomy procedures including a cannula having one end adapted to receive a supply of gas and having a spatula at the opposite end. The spatula has a multiplicity of openings in the forward edge thereof in communication with the bore of the cannula, thus enabling gas to flow through the cannula and out of the opening.

### BACKGROUND OF THE INVENTION

Atherosclerosis or "hardening of the arteries" is a disease of the vascular system which each year is responsible for approximately 800,000 deaths in the United States alone. Basically the disease may be characterized as a build-up of a wax-like plaque upon the inner surfaces of a blood carrying vessel or artery, which reaches such proportion as to block the arterial passageway preventing the natural flow of blood therethrough.

The most common techniques for reconstructing the sections of the vascular system afflicted with arteriosclerosis are "by-pass" or replacement grafts and endarterectomy. The former, as the name implies, consists of the construction of artificial arterial by-passes within the body so as to allow the blood supply to circumvent the inflected arterial section. Endarterectomy procedures once commonly consisted of a surgeon opening large sections of the inflected artery and removing the offending matter by scraping or other procedures. The frequent necessity to fillet the entire length of vessel involved, the tedious dissection required and the all too often incomplete clean out—leading to early thrombosis—motivated the development of the following more efficient endarterectomy procedure.

In this new procedure, the arterial section to be endarterectomized is first isolated from the rest of the arterial system by means of vascular clamps placed proximal and distal the inflected portions. Thereafter a small hollow needle is inserted directly into the sub-adventitial layers of the diseased artery, that is the needle is inserted into the internal layers of the outermost wall of the artery. A jet of carbon dioxide at a pressure of 400 mm. Hg and at a rate of up to 20 liters per minute is then introduced into the artery through the needle bore. The introduction of the carbon dioxide was found to cause the adventitia (outermost wall of the artery) to balloon out, causing a separation of the diseased inner core of sclerotic plaque from the sub-adventitia (inner layer of the outer wall). This inner core of sclerotic plaque consisting of the intima or innermost layer and media must be completely sub-adventitially dissected in order to permit its complete intact removal from the artery, thus alleviating the need for scraping or other clean out procedures.

To assure complete separation and specifically to separate any filamentous bands still connecting the inner core to the sub-adventitia after the initial gas application, two arteriotomies or longitudinal arterial incisions are then made in the isolated arterial section, distal and proximal, and a blunt separating instrument is then passed from the proximal arteriotomy to the distal arteriotomy along the principal plane of dissection of the inner core from the

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sub-adventitia. This reaming of the sclerotic artery assures the complete separation of the diseased inner core from the healthy adventitia and the inner core may then be removed through one of the arteriotomies with conventional forceps after it has been properly transected.

### SUMMARY OF THE INVENTION

The present invention relates to an improved gas endarterectomy needle which simplifies the procedure for assuring complete separation of the inner core from the sub-adventitia by facilitating the severing of any filamentous bands connecting the inner core of sclerotic plaque to the arterial wall after the artery has been inflated as described above.

It is a principal object of this invention to provide a needle which may be used to inject additional quantities of gas proximal to any local area of inner core-adventitia connection and thus aid the dissection therebetween while simultaneously serving as a ream which may be passed along the dissection plane within the vessel and thereby facilitate the eventual removal of the core from the artery.

These and other objects and advantages are most effectively attained by providing a needle comprising a cannula having an internal bore with a first end adapted to receive a supply of gas and an opposite end to which a spatula is affixed. The spatula is a substantially flat member whose width is sufficiently small to permit passage through a human artery. The peripheral edge of the spatula is provided with at least one opening therein and preferably a multiplicity of openings, each such opening being in communication with the cannula bore so as to permit the flow of gas therethrough. All corners and edges of the needle must be blunt and arcuate or rounded to prevent the accidental snagging of the needle on healthy tissue or capillary branches. This is especially true of the leading edge of the spatula. In use, the spatula end of the needle is passed down the endarterectomized vessel along the plane of dissection, that is, the plane of cleavage between the internal core and the adventitia. The spatula is advanced and retracted in the vessel about the core until there is a complete separation of the core from the arterial wall. During this reaming process, gas may be flowing, flowing intermittently, or not flowing at all depending upon the presence and density of connecting matter.

The spatula of the present invention may be planar or it may be saddle-shaped so as to more readily conform to the external surfaces of the inner core.

### DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a top plan view of a gas endarterectomy needle in accordance with the present invention;

FIGURE 2 is a side elevational sectional view along line 2—2 of FIGURE 1;

FIGURE 3 is a sectional view along line 3—3 of FIGURE 2;

FIGURE 4 is an end elevational view of the spatula of FIGURE 1;

FIGURE 5 is a top plan view depicting an alternate spatula design;

FIGURE 6 is an end elevation of the embodiment of FIGURE 5;

FIGURE 7 is a top plan view of a second alternative spatula;

FIGURE 8 is a sectional view along line 8—8 of FIGURE 7;

FIGURE 9 is an end elevation of the saddle-shape spatula of FIGURE 7.

FIGURE 10 is a side elevational view of the spatula of FIGURE 7;

FIGURE 11 is a partially diagrammatic sectional elevational view depicting the initial step of a gas endarterectomy procedure;

FIGURE 12 is a view similar to FIGURE 11 depicting the arteriotomies subsequent to the introduction of the carbon dioxide;

FIGURE 13 is a view similar to FIGURE 12 depicting the needle of the present invention being introduced into the artery;

FIGURE 14 is a view similar to FIGURE 13 diagrammatically depicting the passing of the needle down the vessel;

FIGURE 15 is a view along line 15—15 of FIGURE 11 depicting the relation of the inner core and adventitia; and

FIGURE 16 is a view along line 16—16 of FIGURE 13 depicting the location of the inner core subsequent to the introduction of the needle of the present invention.

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

Reference is now made to FIGURE 1 in particular in which a gas endarterectomy needle 20 in accordance with the present invention is shown. The needle may be made of any material inert to body fluids and compatible with insertion into the human body. Stainless steel has been found to be most satisfactory. The needle is shown comprising a shank portion 22 which includes an exterior support cannula 24 surrounding an internal cannula 26. The shank 22 is affixed at one end 28 to a hub 30 and a spatula 32 at the opposite end 34. The hub 30 may be affixed to the shank 22 by any convenient method such as soldering. The end of the hub 30 distal the shank is adapted to be coupled to a source of carbon dioxide. In this regard, the hub 30 of the needle 20 is provided with a center bore which is in communication with the bore 38 of the internal cannula 26.

The spatula 32 which is affixed to the shank 22 at the end opposite the hub 30 has at least one passageway 40 in communication with the bore 38 of the internal cannula 26. The passageways 40 lead to openings 42 disposed about the forward peripheral edge 44 of the spatula 32. The spatula 32 of the primary embodiment depicted in FIGURE 1 is substantially flat and circular in shape. A manifold 46 is provided within the spatula from which the multiplicity of passageways 40, 40a and 40b branch off. The manifold 46 is substantially a coplanar extension of the bore 38 of the internal cannula 26. In the embodiment of FIGURE 1, passageway 40a is an extension of bore 38 passing straight through the spatula, passageways 40a and 40b are each dislocated at a 60° angle on opposite sides of the passageway 40a.

FIGURE 5 represents an alternate embodiment of the needle of the present invention wherein the shank portion of the needle comprises a single cannula 48. A hub, not depicted is affixed to one end of the cannula in a manner similar to that previously disclosed and a spatula 50 is affixed to the opposite end. The spatula 50 includes a center bore 52 of substantially the same diameter as the bore 54 of the single cannula 48. Passageways 56 are provided in communication with the center bore 52 and having openings 58 disposed about the forward peripheral edge 60 of the spatula 50 in the embodiment depicted. Opening 58a and its corresponding passageway 56a represent a substantial continuation of the bore 54 through the spatula 50. Thus, opening 58a is diametrically opposite the connecting surface 62 where the cannula 48 is affixed to the spatula 50.

FIGURE 7 represents a third alternate embodiment of the spatula portion of the needle of the present invention. In this alternate embodiment, the spatula 64 is substantially saddle-shape as seen in FIGURE 9. This enables the spatula to more conveniently slide over the inner core of the atherosclerotic artery during use. The shank 66 of this alternative embodiment may consist of either the single or double cannula constructions described in the previous embodiments. Also, as in the previous embodiments, a multiplicity of openings 68 are provided in the for-

ward peripheral edge 70 of the spatula 64, that is the portion of the peripheral edge substantially opposite the point of attachment 72 of the shank 66 to the spatula 64. The spatula 64 is provided with a manifold bore 74 which is in communication with the cannula bore 76. Passageways 78 are provided in communication with the manifold bore 74 in a manner similar to that described in the previous embodiment and at least one passageway 78b represents a direct continuation of the cannula bore 76 through spatula.

Thus it can be appreciated that in all embodiments when a supply of gas is connected to the hub portion 30 and permitted to flow through the shank 22 of the needle, streams of gas will emanate through the various openings in the forward peripheral edge of any particular spatula. The size of the spatula should be such as to enable its introduction within the arterial system of a human being. For practical purposes, the width of the spatula may range between  $\frac{1}{8}$  and  $\frac{7}{16}$  inch.

The operation of the gas endarterectomy needle in accordance with the present invention may best be appreciated in conjunction with FIGURES 11 through 14. In FIGURE 11 a section of artery 80 inflicted with atherosclerosis is depicted as it is being prepared for a gas endarterectomy procedure. The section 80 is isolated from the remainder of the vasculature by the vascular clamps 82 and 82a and multiple injections of carbon dioxide gas are introduced into the sub-adventitial through angular needle 84. The depth of the needle determines the location of the dissecting plane, that is the plane at which the inner core will separate from the adventitia. The introduction of the gas has the effect of dissecting the inner surfaces of the outer or adventitial layers 86 of the wall of the artery 80 from diseased inner core 88. However, filamented strands 90 may still serve to connect the diseased inner core and outer wall 86. Short longitudinal arteriotomies 92 are then made through the outer wall in a standard manner thus exposing the inner core 88. As shown in FIGURES 13 and 14 the gas endarterectomy needle 20 in accordance with the present invention may then be passed down through the vessel along all the surfaces of the exposed core 88 thus ensuring the complete freedom of the core from the filamented strands 90. The spatula may be passed down the vessel with or without the gas flowing depending on the number and density of filamented strands 90. The inner core is then transected distally and proximally and extracted from the artery. The arteriotomies may be then closed in a standard fashion and the clamps 82 removed. These last procedures, not being depicted.

It should be understood that the gas endarterectomy procedure technique disclosed herein does not form a part of the present invention and that the present application is directed only at the instrumentation which facilitates this technique.

It should be further understood that modifications may be made in the illustrated and described embodiments of our invention without departing from the invention as set forth in the accompanying claims.

We claim:

1. A needle useful in endarterectomy procedures including a shank portion having an internal longitudinal bore therethrough and having a first end adapted to receive a supply of gas and a spatula affixed to the opposite end, a plurality of openings in the peripheral edge of said spatula, and a plurality of passages disposed internal said spatula and extending between said shank portion internal bore and said peripheral edge openings serving to connect said openings to said bore.

2. The invention in accordance with claim 1 wherein said spatula comprises a substantially flat circular disk coplanar with said shank portion.

3. The invention in accordance with claim 1 wherein said shank portion comprises a first cannula surrounded by and disposed within a second supporting cannula and

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wherein said internal bore comprises the bore of said first cannula.

4. The invention in accordance with claim 1 wherein said spatula comprises a saddle-shaped member having a crown portion and side portions arcuately depending from said crown wherein said crown portion forms a substantial continuation of said shank.

5. The invention in accordance with claim 1 wherein said first end is provided with a hub.

6. The invention in accordance with claim 1 wherein all edges of said needle are blunt and arcuate.

7. A needle useful in endarterectomy procedures including a shank portion having an internal longitudinal bore therethrough and having a first end adapted to receive a supply of gas and a spatula affixed to the opposite end, said spatula having a peripheral edge with at least one opening therein in communication with said shank portion internal bore wherein all the edges of said needle are blunt and arcuate.

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L. W. TRAPP, Primary Examiner

U.S. Cl. X.R.

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