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(71) Applicant: W.L. GORE & ASSOCIATES, INC. [US/US]; 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714 (US).

(72) Inventor: NELSON, Eric, D.; 4035 N. Lugano Way, Flagstaff, AZ 86004 (US).

(74) Agents: CAMPBELL, John, S. et al.; W.L. Gore & Associates, Inc., 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714-9206 (US).

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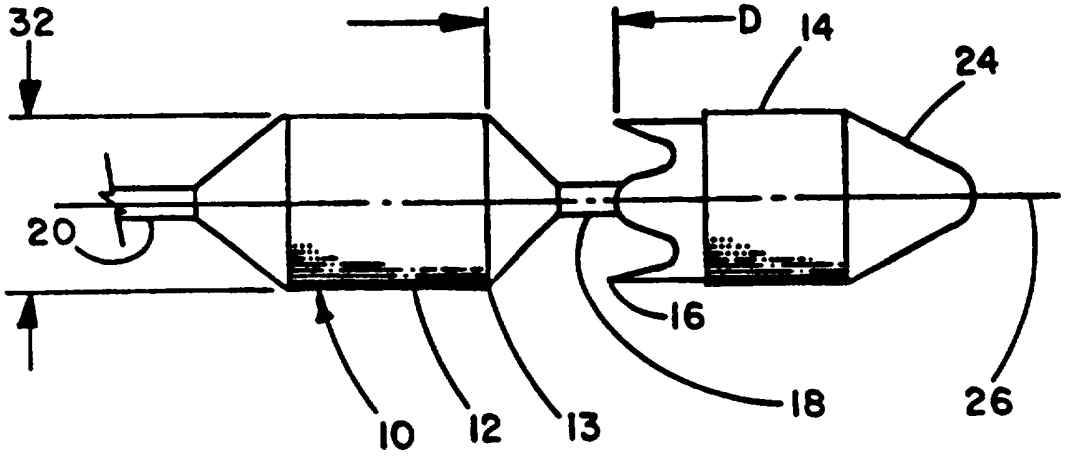

(57) Abstract

A 2.5 mm diameter and larger valvulotomes having a cutting bulb incorporating at least one cutting edge and a leading bulb wherein the cutting bulb and leading bulb are connected along their common longitudinal axes and wherein the bulbs are separated by a distance between 1.3 mm and 2.5 mm.

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A VALVULOTOME

FIELD OF THE INVENTION

This invention relates to the field of surgical devices used for vascular surgery and specifically for the disabling of venous valves.

BACKGROUND OF THE INVENTION

The terms proximal and distal are used herein to mean, respectively, nearer to or farther from the heart. With respect to a valvulotome, these describe ends of the device or components of the device as used in a living vein as the opposite ends of that vein are oriented with respect to the heart.

Arterial reconstruction involving an autologous saphenous vein is common in the field of peripheral vascular surgery in the lower extremities and in coronary bypass surgery. In peripheral vascular surgery, in situ bypass grafting has become more and more the operation of choice for bypassing the infrageniculate arteries and re-establishing arterial blood flow. The autogenous saphenous vein has also been shown historically to perform effectively as an artery in vascular cardiac bypass surgery.

The earliest work with venous autogenous grafts was by Gluck in 1894, followed by Exner and Hopfner in 1903. In the United States, Julian et al., Lord and Stone, Dale et al., and Linton and Darling pioneered the wide use of an autologous vein in femoral-popliteal arterial reconstructive procedures. The concept of using the saphenous vein in situ is attributed to Karl Hall who suggested in 1959 that the saphenous vein bypass might improve if the vein were left in place and the valves were rendered incompetent. He was the first to successfully report the use of the in situ procedure as an arterial bypass in 1962. The technique of in situ bypass grafting was further augmented by Leather and Karmody who used valve strippers to disrupt the vein valves.

With the increasing experience worldwide, it was apparent that the crux of the in situ vein graft was the method of removal of the valvular obstruction to distal arterial flow.

Leather described that it "has been found that the simplest, most expedient and least traumatic method of rendering the bicuspid venous valve incompetent is to cut the leaflets in their major axes while they were held in the functionally closed position by fluid flow or arterial pressure from above."

In order to accomplish this purpose, Leather stated that it is necessary to expose both proximal and distal sites of the vein. A rod is inserted through the distal incision and through the vein until it exits at the proximal incision. A valve cutter is attached to the rod and a catheter is sutured to the valve cutter. The valve cutter is then drawn into the vein through the proximal incision. Fluid supplied by the catheter keeps the valve leaflets closed during the retrograde motion of the cutter through the vein from proximal to distal sites.

An early commercially available valvulotome for the disruption of venous valves is the so-called "Mills retrograde valvulotome," which consists of an elongated rod having an L-shaped end with a bulbous tip and a blade located between the bulbous tip and the elongated portion of the rod and facing in the direction of the elongated rod. The end of the valvulotome is passed through a valve and the instrument is then pulled in the reverse direction, causing the blade to cut through a valve leaflet. With this instrument, two or more passes are necessary for each valve set to insure that both valve leaflets are sufficiently destroyed to permit arterial flow of blood.

More recent designs of valvulotomes have evolved from work done by Dr. Peter Samuels into a form best described as a length of rod or cable having a pair of bulbs affixed to the proximal end of the rod or cable, the bulbs being separated by a relatively short length of the rod or cable. Both bulbs and the rod or cable share a common longitudinal axis. The bulb at the very end of the rod or cable is commonly referred to as the cutting bulb and incorporates one or more cutting edges at the end of the cutting bulb opposite the extreme end of the device and closest to the other bulb, which is commonly referred to as the leading bulb. In use, the length of rod or cable

with the attached pair of bulbs is inserted into a vein via an incision made to provide access to the distal end of the vein and inserted in the same direction as the normal flow of blood through the vein. Both bulbs typically have tapered, pointed proximal ends so that they easily enter and pass through any venous valves encountered, the tapered, pointed bulb ends causing the valve to open around the passing bulbs. After being passed through all of the venous valves which are intended to be rendered incompetent by this procedure, the length of the rod or cable with the attached bulbs is then carefully withdrawn. The leading bulb then first encounters each valve. This bulb, having a distal end which is also tapered or pointed, again passes through the valve, this time in a direction opposite to that of normal blood flow through the vein. The leading bulb holds the cutting bulb concentric within the vein with respect to the valve as a function of the respective diameters of the vein and the leading bulb. As the rod is withdrawn, the venous valve closes behind the leading bulb and around the short length of rod or cable connecting the two bulbs. As the rod is continued to be withdrawn, the cutting edge or edges of the cutting bulb encounter the valve and render the valve incompetent by preferably cutting the valve along its major axis while leaving the least possible amount of valve material attached to the luminal vein surface. This result has been difficult to achieve consistently with presently available devices of this type without also cutting into the lumen of the vein and causing luminal damage. This luminal damage to the vein primarily results from the cutting edge of the cutting bulb catching on tributaries to the vein or on the lumen of the vein as it tapers.

SUMMARY OF THE INVENTION

According to the present invention, it has been discovered that the space between the leading bulb and cutting bulb of commercially available two-bulb valvulotomes of about 2.5 mm diameter and larger is excessive and the risk of damage to the vein is reduced and the performance of the valvulotome is considerably improved if the space between the two bulbs is less than 3.5 mm and preferably less than

about 2.5 mm. Likewise this distance should be greater than about 1.3 mm to maintain the cutting ability of the valvulotome. 2.5 mm and larger diameter valvulotomes having this distance less than or equal to 2.5 mm considerably reduce the risk of the cutting edge inadvertently catching on a tributary vein or on the wall of the saphenous vein. The distance should be greater than about 1.3mm in that lesser distances result in inadequate valve lysing, wherein significant valve remnants are left behind following lysing.

Previously described valvulotomes of about 2 mm diameter have specified relatively small bulb spacings of less than about 2.5 mm. All larger valvulotomes have specified larger distances on the premise that the spacing should increase commensurate with increases in diameter. According to the present invention, it has been discovered that larger valvulotomes are more effective if smaller bulb spacings are used.

This bulb spacing distance is measured from the apex of the cutting edge of the cutting bulb closest to the leading bulb, to the point of largest diameter of the leading bulb closest to the cutting bulb, that is, the point at which the diameter of the leading bulb begins to taper and therefore reduce.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1A and 1B describe side views of valvulotomes of the present invention.

Figure 2A describes a side view that defines distance D between the cutting edge and the leading bulb for a valvulotome having a leading bulb with tapered sides.

Figure 2B describes a side view that defines distance D between the cutting edge and the leading bulb for a valvulotome having a leading bulb with a rounded distal end.

Figure 3 describes a side view showing a method of quantitatively evaluating valve lysis.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1A describes a side view of a valvulotome 10 of the present invention having a leading bulb 12 and a cutting bulb 14 attached to a length of rod or cable 20, typically a guidewire, at the proximal end 24 of the valvulotome 10. The length of rod or cable 20 is most commonly in the form of a guidewire. The two bulbs 12 and 14 are typically connected by a short length of rod 18, all sharing a common longitudinal axis 26. Leading bulb 12 has a maximum diameter 32 and a point 13 with respect to the longitudinal axis 26 which represents the point of closest proximity of maximum diameter 32 to the apex 16 of the cutting edge or edges of cutting bulb 14. The present invention relates to the discovery that the effectiveness of a valvulotome is related to this distance D between closest point 13 of the maximum diameter 32 of leading bulb 12 and the cutting edge or edges 16 of the cutting bulb 14 closest to the leading bulb 12. Distance D is always measured parallel to the longitudinal axis 26 of the valvulotome 10. It has been found that if this distance D is between 1.3 and 2.5 mm, the effectiveness of the valvulotome is significantly increased.

Figure 1A describes a valvulotome having a cutting edge with multiple apexes 16 from which distance D is measured. Conversely, the cutting edge may be of circular form with only a single, continuous apex 16 as described by Figure 1B. Distance D is measured from this single, continuous apex.

Figures 1A and 1B describe valvulotomes 10 having leading bulbs 12 with straight sides that are parallel to the common longitudinal axis 26 wherein leading bulb end nearest the cutting bulb tapers abruptly from its maximum diameter 32 as it approaches the cutting bulb. Figure 2A describes a valvulotome having a leading bulb with a slight, gradual taper wherein the largest diameter 32 occurs at the end opposite the cutting bulb 14. Figure 2B describes a valvulotome having a leading bulb with a rounded end nearest the cutting bulb 14. For valvulotomes of the types described by Figures 2A and 2B, the distance between the cutting edge of the cutting bulb closest to the leading bulb and the point of the effective largest diameter of the leading bulb closest to the cutting bulb is measured as described by

Figures 2A and 2B. The distance, referred to in Figures 2A and 2B as distance D, is measured along a first line 41 through the largest diameter 34 of the cutting bulb 14 and parallel to the common longitudinal axis 26. Distance D extends from the cutting edge 16 of the cutting bulb 14 that is closest to the leading bulb 12, to a point A defined as follows. Point A lies at the intersection of the first line 41 and a second line 43. The second line 43 begins at point B defined by the intersection of the common longitudinal axis 26 and a third line 45 through and perpendicular to the common longitudinal axis 26 and through the at least one cutting edge 16 of the cutting bulb 14 closest to the leading bulb 12. The second line 43 extends from point B through a tangent point T on the surface of leading bulb 12, wherein tangent point T is the closest possible tangent point to cutting bulb 14. For example, if leading bulb 12 is asymmetrical about the common longitudinal axis 26 then it is important that the third line 45 extends through tangent point T which lies closest to cutting bulb. When distance D is determined by this method, distance D is preferably between 1.3 and 2.5 mm. Distance D for a commercially available valvulotome having a leading bulb with a rounded distal end, a Leather® 2 mm diameter valvulotome (Baxter Healthcare Corporation, Deerfield, IL; Catalog No. CH8686-1), measures 3.2 mm by this method.

To determine the effectiveness of different dimensions for distance D, two stainless steel valvulotomes were made up using device geometries as shown by Figure 1A and described in further detail by PCT Publication Number WO93/20764. Leading bulbs 12 and cutting bulbs 14 were provided with female screw threads intended to mate with male screw threads at both ends of connecting rod 18. Distance D was then adjustable according to the degree of engagement of the screw threads. The two valvulotomes differed in that one was provided with a maximum leading bulb diameter of 2 mm while the other was 3 mm. The maximum diameter of the leading bulb was the same as the cutting bulb for both devices. Both devices were provided with cutting edges having four apexes and four recesses with the entire edge including apexes, recesses and points between being sharpened.

It also is anticipated that a distance D between 1.3 and 2.5 mm will also be effective for valvulotomes of diameters larger than 3 mm.

Distance D was adjusted to various dimensions for both the 2 mm

and 3 mm diameter valvulotomes. For each chosen dimension for distance D, the effectiveness of each valvulotome was tested on cryopreserved human veins at room temperature. The effectiveness was determined by noting the number of times that any cutting edge of the valvulotome caught at any point within the lumen of the vein other than at the attachment point of venous valves. Effectiveness was also measured by opening each vein longitudinally after valve lysis and measuring how much ridge of any lysed valve remained as shown by Figure 3.

Cryopreserved human veins were obtained from Northwest Tissue Center, Seattle WA. All veins had been obtained from donors 65 years of age or younger within 12 hours of death. Cryopreserved human vein has been found to substantially maintain the mechanical and physical properties of living human vein. No veins with a prior history of trauma, varicosity or infection were used. Veins having undistended inside diameters from 1.9 to 3.7 mm and lengths between 25 and 45 cm were used. The number of venous valves per vein ranged from zero to four with two or three being typical.

A cryopreserved vein with its proximal end marked was rewarmed in Lactated Ringer's Solution to room temperature and irrigated with the same solution containing 0.5% papaverine by volume. Extraneous tissue was dissected away and all side branches except the most proximal were ligated.

A second flushing catheter was connected to the remaining, most proximal tributary in order to provide a 100 mm Hg pressure head with the Lactated Ringer's Solution ensuring closure of the venous valves within the vein sample. The proximal end of the vein was clamped off. An inventive valvulotome was introduced to the vein sample distally and passed to the proximal end. The location of venous valves was noted during this procedure. After reaching the proximal end of the vein, the valvulotome was withdrawn by hand back toward the distal end of the vein while paying close attention to the force required to move the valvulotome through the vein and through venous valves as they were encountered by the cutting edge of the valvulotome. Any tendency for the valvulotome to hang up at any point in the vein other than at valves was noted with particular attention paid to any increase in pulling force as the cutting edge of the valvulotome passed the point

of attachment of each tributary of the vein. This tendency if any was recorded for each vein as a measure of the quality of valve lysis.

Following lysis of all valves from each vein, the flow of fluid from the pressure source out of the proximal end of the vein was noted as an indication of valve lysis. After removal of the valvulotome, a fiberscope was inserted into the vein from the distal end to confirm valve lysis. After removal of the fiberscope, the vein sample was cut open longitudinally for the entire length of the sample to allow inspection of valve lysis.

As shown by Figure 3, the degree of valve lysis was evaluated by sliding the pointed tip 52 of a pair of Potts Tenotomy scissors 54 (Part No. 640280, WECK Surgical Instruments, Largo, FL) along the luminal surface of the longitudinally opened vein 51 in a direction 56 parallel to the length of the vein, from the proximal end 57 toward the distal end 58 with the tip pointed toward the distal end. The scissors were held at an angle 55 of about 45° with respect to the luminal surface 50 of the vein 51 with the plane of the scissors handles 59 perpendicular to the luminal surface 50 of the vein 51. In this fashion, the pointed tip 52 of the scissors 54 would catch on any appreciable ridge 60 of valve tissue remaining attached to the luminal surface 50 vein 51. As the thickness the scissors tip 52 including both blades of the scissors 54 was about 1.0 mm, it was possible to estimate the amount 53 of valve ridge 60 remaining attached to the luminal surface 50 of the vein 51, if any. Both valve leaflets of each valve were measured in this fashion with the aid of 8X stereoscopic magnification. The largest amount of remaining ridge 60 so measured was recorded for each tested vein as an indication of lysis quality for that vein. The results for all veins tested for each of the 2 mm and 3 mm valvulotomes were recorded. Veins were tested with the valvulotomes set at various bulb separation distances D as noted in Table 1. The table describes the undistended inside diameter of each vein sample tested, distance D for the valvulotome, the number of valves encountered in the vein sample, the number of valves considered to have been lysed by the valvulotome, the remaining amount of valve ridge as encountered by the scissors tip and the number of times the valvulotome caught at any point within the lumen of the vein other than at valve attachment points (number of hang-

ups). For vein sample No. 2, the remaining amount of valve ridge was not recorded.

Samples A-C were veins lysed using 3 mm diameter valvulotomes having a bulb separation distance D of 6.0 mm. A total of eight valves were lysed from these three veins. Of these eight valves, two leaflets were left with ridges greater than 1 mm, and three hang-ups occurred, for a total of five failure incidents or 62.5 percent for eight valves.

Samples D-H were veins lysed using 3 mm diameter valvulotomes of the present invention having bulb separation distances of 1.3 to 2.5 mm. These valvulotomes were used to lyse a total of eleven valves from the five veins. One valve leaflet was left with a ridge dimension of greater than 1.0 mm and no hang-ups occurred, for a failure rate of 9 percent for the eleven valves from this group.

Samples I-K were veins lysed using 3 mm diameter valvulotomes having a bulb separation distance D of 1.0 mm or less. A total of five valves were lysed with four valve leaflets having remaining ridges of greater than 1.0 mm and with no hang-ups, for a failure incidence of 80 percent. Clearly, the 3 mm valvulotomes having bulb separations in the inventive range were safer and more effective than were units with bulb separations outside of the inventive range. The data for the 3 mm diameter valvulotomes were consistent with the 2 mm diameter valvulotome data, indicating that the preferred spacing of the valvulotome bulbs is independent of device diameter. The consistency of the data also indicate that similar results could be expected of valvulotomes of about 2.5 mm diameter.

From this testing it is apparent that at long bulb spacings of 5.4 to 6.0 mm a valvulotome will catch unexpectedly on the inside of a vein a high percentage of the time (100% for 2 mm diameter devices and 67% for 3 mm diameter devices). This testing confirms clinical experience which reports on problems with valvulotomes catching on the inside of veins and at the site of tributary side branches. Conversely, this testing also demonstrates that short bulb spacings of less than 1.3 mm result in inadequate lysing of venous valves (33% of valves lysed with the 2mm diameter device and 20% of valves lysed with the 3 mm diameter device).

TABLE 1

EFFECTIVENESS OF VENOUS VALVULOTOMES

2 mm Diameter Valvulotome:

Vein Sample	Vein Diameter (mm)	Valvulotome Distance D (mm)	Valve Sets/ Percent Lysis	Ridge Dimension (mm)	Number of Hang-Ups
1	2.5-3.0	5.40	4/100	0-1	2
2	2.4	5.40	0/0	N/R	1
3	2.8	5.40	2/100	0	1
4	2.2-2.9	3.50	3/100	0-0.5	0
5	2.55	3.50	1/100	0	0
6	3.5	3.0	1/100	0-0.5	0
7	2.7	3.0	1/100	0	0
8	2.7	3.0	2/100	0-0.25	0
9	2.5	2.40	2/100	0	0
10	1.9	2.40	1/100	0+	0
11	2.4	2.15	3/100	0-1	0
12	2.8	1.90	1/100	0	0
13	2.7	1.90	2/100	0+	0
14	2.5	1.90	2/100	0-0.5	0
15	1.9	1.90	3/100	0-0.75	0
16	2.5-3.0	1.40	4/100	1-3	0
17	2.6	1.40	1/100	0-1	0
18	2.2-2.9	1.15	3/33	0-4	0

3 mm Diameter Valvulotome:

Vein Samples	Vein Diameter (mm)	Valvulotome Distance D (mm)	Valve Sets/ Percent Lysis	Ridge Dimension (mm)	Number of Hang-Ups
A	3.0-3.5	6.0	4/100	0-1	0
B	2.6-2.9	6.0	3/100	0-1,0-2.0	2
C	2.7	6.0	1/100	0-2.5	1
D	2.6-3.0	2.5	3/100	0-1.0,0,0-0.5	0
E	3.0-3.5	1.5	3/100	0+	0
F	2.9	1.5	1/100	0-2.5	0
G	2.6	1.5	3/100	0-0.25	0
H	2.4	1.3	1/100	0-0.5	0
I	2.4-3.0	1.0	3/83	1.0-4.0,0,1.5-2.5	0
J	2.6	0.8	1/100	0-1.5	0
K	3.7	0.8	1/50	2.0-3.5	0

I Claim:

1. A valvulotome comprising a leading bulb having a diameter of at least about 2.5 mm and a cutting bulb having a diameter of at least about 2.5 mm, said cutting bulb having at least one cutting edge adjacent to the leading bulb wherein said leading bulb and said cutting bulb are connected along a common longitudinal axis and said leading bulb and said cutting bulb are separated by a distance from the maximum diameter of the leading bulb closest to the cutting bulb to the at least one cutting edge of the cutting bulb closest to the leading bulb, said distance being between about 1.3 and 2.5 mm.
2. A valvulotome according to claim 1 wherein the leading bulb and cutting bulb each have a diameter of at least about 3 mm.
3. A valvulotome according to claim 1 wherein the leading bulb and cutting bulb each have a diameter of at least about 3.5 mm.
4. A valvulotome according to claim 1 wherein the leading bulb and cutting bulb each have a diameter of at least about 4 mm.
5. A valvulotome comprising a leading bulb having a diameter of about 3 mm and a cutting bulb having a diameter of about 3 mm, said cutting bulb having at least one cutting edge adjacent to the leading bulb wherein said leading bulb and said cutting bulb are connected along a common longitudinal axis, said valvulotome having a distance D between the at least one cutting edge of the cutting bulb closest to the leading bulb and a point A, wherein said distance D is measured along a first line through the largest diameter of the cutting bulb and parallel to the common longitudinal axis, wherein said distance D is between about 1.3 mm and 2.5 mm, and wherein point A is defined as the intersection of the first line and a second line, said second line beginning at a point B defined by the intersection of the common longitudinal axis and a third line through and perpendicular to the common longitudinal axis and through the at least one cutting edge of the cutting bulb closest to the leading bulb, said second line extending from said point B through a tangent point on the surface of said leading bulb, said tangent point being the closest possible tangent point to the cutting bulb.

6. A valvulotome according to claim 5 wherein the leading bulb and cutting bulb each have a diameter of at least about 3 mm.

7. A valvulotome according to claim 5 wherein the leading bulb and cutting bulb each have a diameter of at least about 3.5 mm.

8. A valvulotome according to claim 5 wherein the leading bulb and cutting bulb each have a diameter of at least about 4 mm.

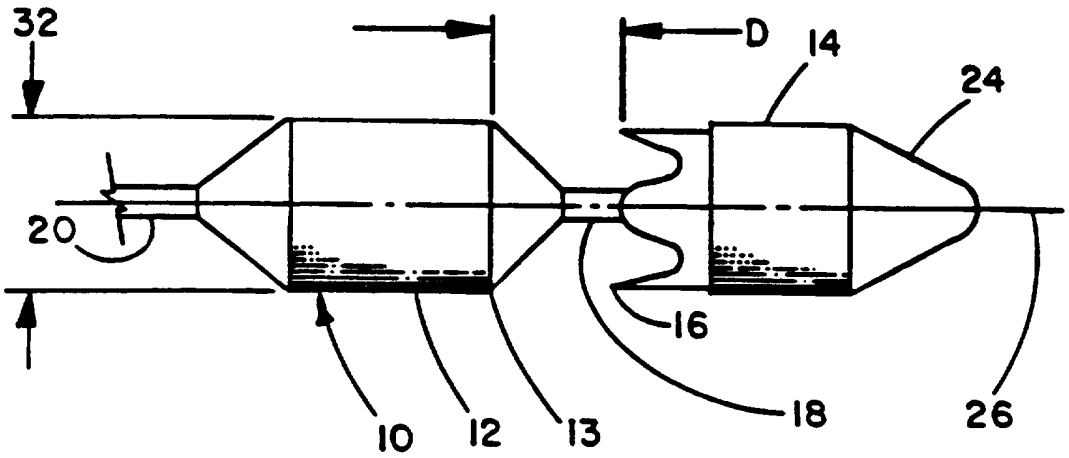

FIG. 1A

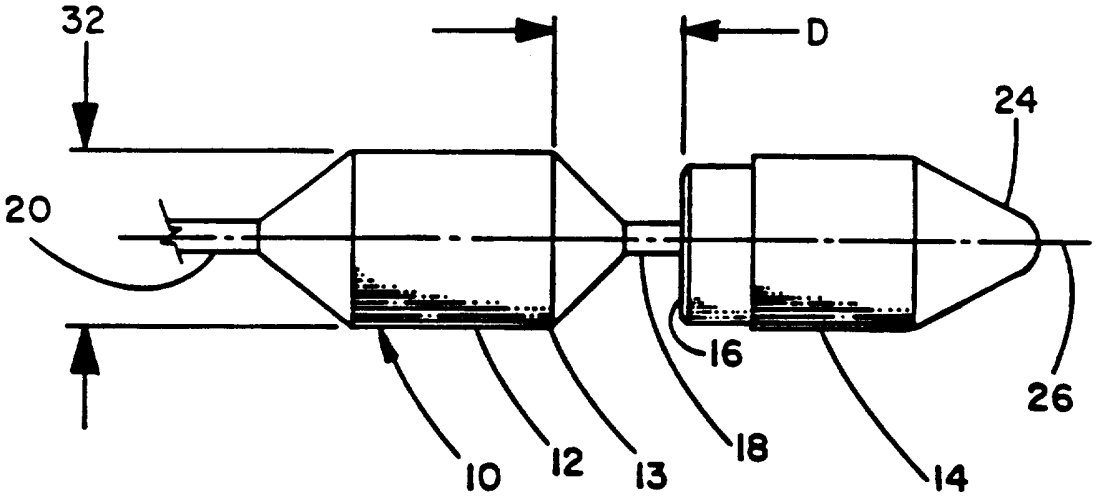

FIG. 1B

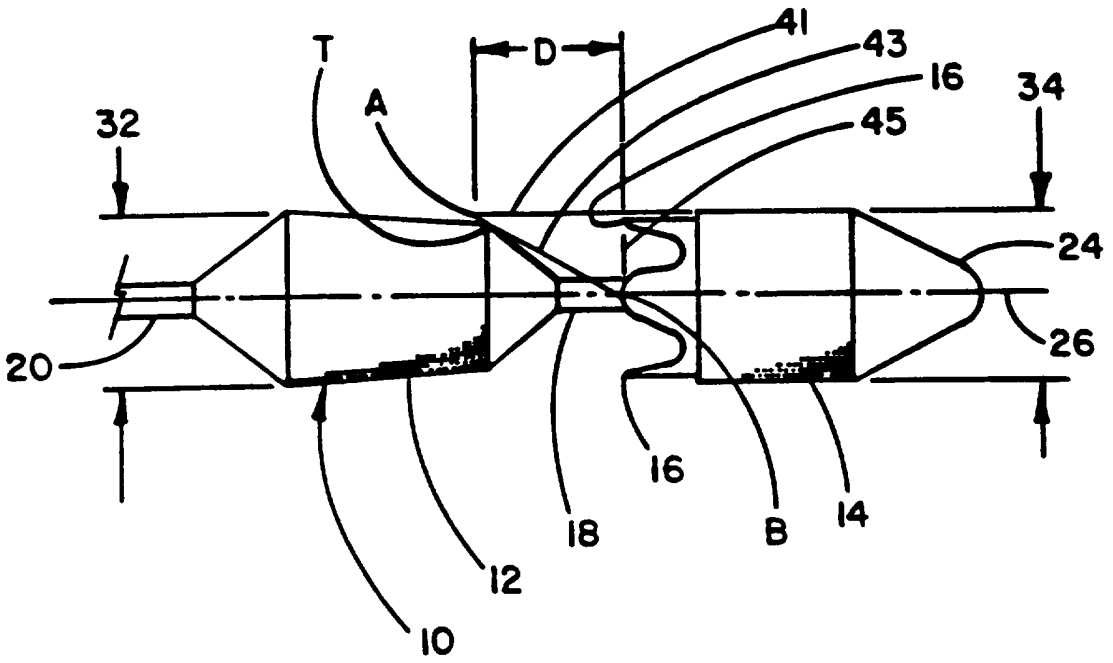
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FIG. 2A

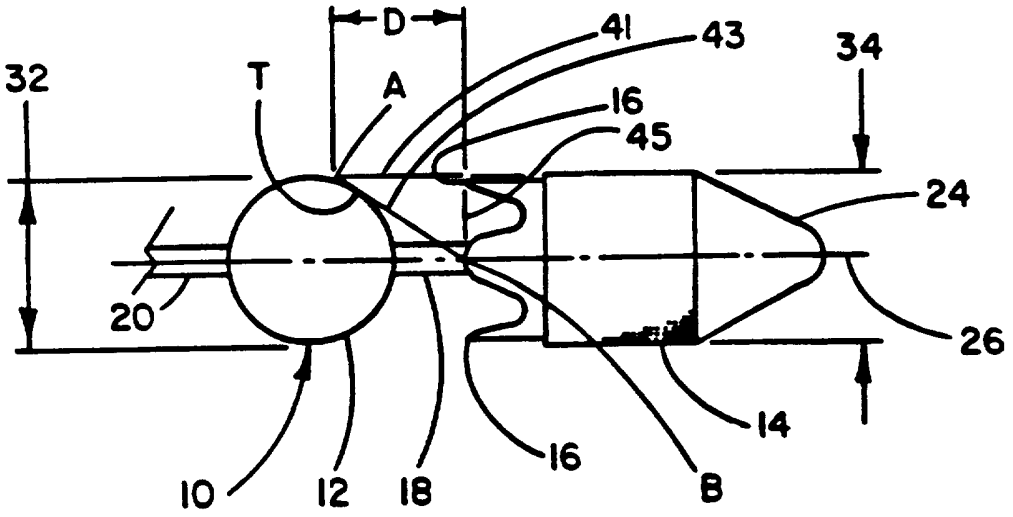
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FIG. 2B

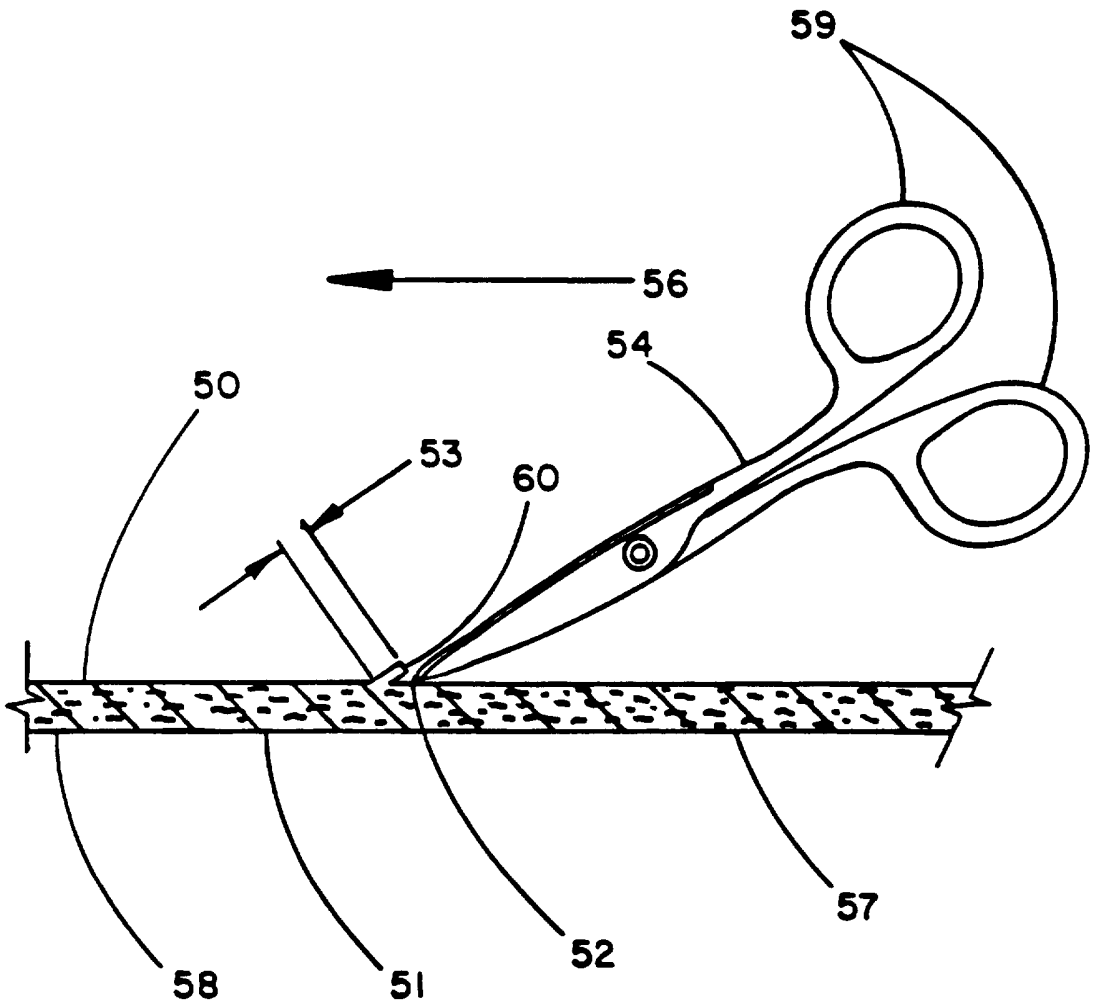

FIG. 3

INTERNATIONAL SEARCH REPORT

Interr al Application No
PCT/US 96/13836

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/22

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)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 139 506 A (BUSH RONALD G) 18 August 1992 see column 3, line 1 - line 13 see figure 1 ---	1-8
P,X	WO 95 28888 A (GORE & ASS) 2 November 1995 see page 6, line 15 - line 34 see page 7, line 11 - line 12 see page 9; table 1 see figures 1A-3 ---	1-8
A	WO 93 20764 A (URESIL CORP ;GOLDBERG MARK (US); POLOYKO ALEXANDER (US); GOLDBERG) 28 October 1993 cited in the application see page 11, line 15 - line 20 see figures 1,2,4A,5,9 --- -/--	1-8

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
10 February 1997	21. 02. 97

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European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Chabus, H

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 40 19 147 A (NOBLES LAI ENGINEERING INC) 7 February 1991 see column 5, line 2 - line 17 see figure 6 -----	1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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PCT/US 96/13836

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