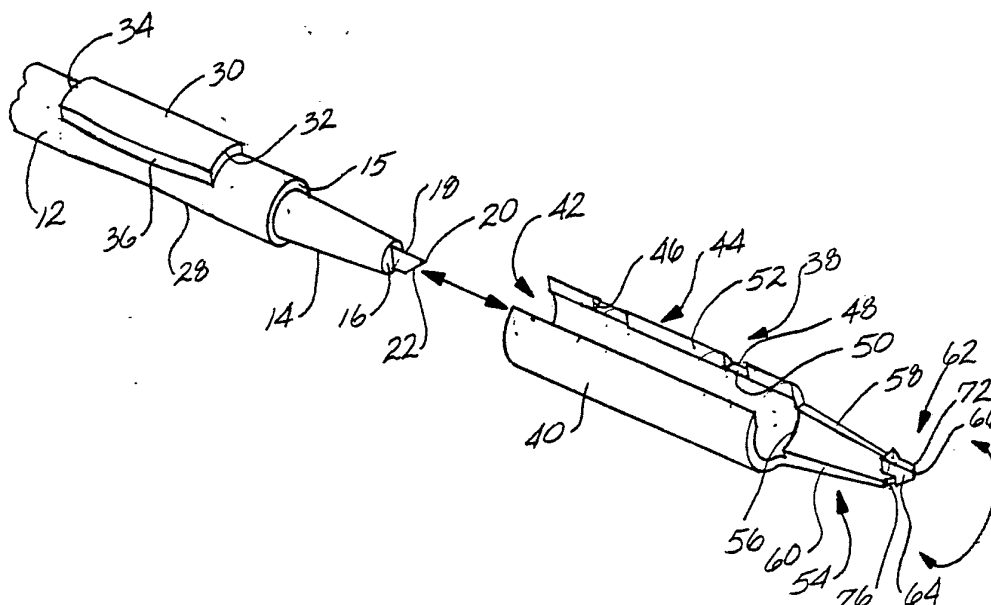


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(54) Title: SCALPEL WITH REMOVABLE DEPTH GUARD



(57) Abstract

A scalpel (10) is set forth having a handle (12) with a blade (18) at one end which defines a first depth of cut (A). To transform the scalpel (10) for cutting to a lesser second depth of cut a removable guard (38) is provided. The guard (38) is attached to the scalpel handle (12) with a bayonet-type connection and has a tip (62) to be disposed near one side of the blade (18). When the guard (38) is attached, the blade (18) projects past the tip (62) a predetermined amount to define the second depth of cut (B). Guards (38) are constructed for right or left hand preference.

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10 SCALPEL WITH REMOVABLE DEPTH GUARD

Field of the Invention

15 This invention relates to surgical scalpels and more particularly to scalpels adapted for surgeries where precise incisions are desired or required such as cataract surgery, plastic surgery, vascular surgery, orthopedic surgery or the like.

Background of the Invention

20 In certain surgical procedures, it is often highly desirable that smooth, precise, continuous incisions of a controlled depth be made. Irregular or discontinuous incisions may result in complications in healing and cause an irregular and perhaps enlarged scar. An imprecise incision may result in wound leakage or, in particular, in cataract surgery, in astigmatism.

25 With particular reference to cataract surgery, an initial incision is required at the sclera of the eye adjacent the cornea, the incised tissue being retracted to gain access to the lens of the eye. This incision is typically made along an arc following the curvature of the cornea. According to the prior art, the surgeon would by hand make an initial incision groove and following the groove, a subsequent intraocular incision to gain access to the lens.

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1 The tissue of the sclera being incised typically has
a thickness of between 300-700 microns. To limit the
depth of cut, various scalpels have been devised as described
in U.S. Application Serial No. 567,263 filed December 30,
5 1983 and entitled "Disposable Ophthalmic Instrument for
Performing Radial Keratotomy on the Cornea." The scalpel
according to this application is adapted, using external
gauges or the like, to have a selected depth of cut.

Cutting initially to the required depth, i.e., to
10 incise the sclera, may result in an irregular or perhaps
imprecise cut due to the resistance of the relatively
large amount of tissue being incised and the fact that the
incision is being made by hand. It would be advantageous,
if an initial incision in the sclera of a nominal depth
15 could first be made by the surgeon, the initial incision
defining a line for the ultimate, complete incision to be
made. To provide for a regular closure of the incision
and to prevent wound leakage and astigmatism, the final
incision is made at an angle (beveled). Using this initial,
20 nominal depth incision, the surgeon could then retrace the
incision cutting to the desired depth, the initial incision
acting as a guide.

Given the problem and the desired solution, the
applicant has achieved desired results by using a pair of
25 scalpels. A first scalpel, having a preset nominal depth
of cut, was used to make the initial incision. In that a
relatively shallow depth cut was being made a smooth,
precise and continuous initial incision could be made.
Thereafter, a second scalpel having a deeper depth of cut
30 was inserted into the initial incision and, using that
initial incision as a guide, was positioned at the correct
cutting angle and was moved to retrace the initial incision
and complete the intraocular incision. The smooth, precise
and continuous incision defined by this procedure has been
35 found advantageous in that the incision when closed by

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1 suturing forms a watertight closure and prevents astigmatism.

Of course, it is to be understood that this procedure could apply equally well to surgeries other than those involved with the eye, such as cosmetic or other surgeries
5 involving the skin where precise wound closure is necessary.

The use of two or more scalpels, one set to have a preset depth of cut, is costly since the scalpels are usually discarded. Further, the use of a pair of scalpels may be time consuming and frustrating to the surgeon since
10 the surgeon must change from the first to the second scalpel.

Summary of the Invention

There is, therefore, provided in the practice of the present invention a scalpel which is transformable via a
15 removable guard, between a condition at which it is adapted to make an initial incision to a predetermined, nominal first depth to a second condition at which it is adapted to make an incision to a greater second depth to complete the incision. For surgical techniques using cataract
20 surgery as an example, only one scalpel need be used and hence a cost savings can be realized. Further, the smooth, continuous and precise incision made by the scalpel promotes success of the procedure. Of course, the scalpel according to the present invention has applications to other surgical
25 techniques other than those involved with the eye.

Toward this end the scalpel, according to the present invention, includes a handle having at one end a cutting blade, which may or may not have a predetermined, fixed depth of cut. For cataract surgery, the blade is disposed
30 on the handle such that its depth of cut is greater than the thickness of the scleral tissue. The scalpel also includes a guard having a tip and means for quickly and detachably coupling the guard to the handle. The coupling means includes means for locating the guard at a
35 predetermined position on the handle whereat the tip is

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1 disposed proximate the blade and the blade projects past
the tip a predetermined amount defining a nominal depth of
cut for the initial incision. With the guard on the handle,
the surgeon makes the initial incision to a nominal depth
5 predetermined by the relationship between the guard tip
and the blade. After the initial incision has been
completed, the surgeon quickly and easily detaches the
guard, reinserts the cutting blade into the initial incision
and retraces the initial incision completing the cut to
10 the required depth.

In the preferred embodiment, the coupling means includes
a rectangular key disposed on the handle near the tip, the
key preferably aligned with the blade to aid the surgeon's
grasp of the handle and for aligning the blade in the hand
15 by simply feeling the location of the key. The coupling
means further includes a slot disposed on the guard to
receive the key as the guard is inserted over the handle
one end. Once the guard has been disposed over the handle
one end it is rotated to precisely locate the key in a
20 pocket firmly coupling the guard to the handle and precisely
locating its tip relative to the blade. The key and pocket
are precisely positioned during the manufacture thereof so
that a predetermined relative position between the guard
tip and blade is had when the guard is coupled to the handle.

25 The guard may be fashioned to include a sleeve having
the aforementioned slot and pocket and a projecting arm
the end of which defines the tip. During the initial
incision, the scalpel is held by the surgeon such that the
tip does not obstruct the surgeon's view of the initial
30 incision being made. That is, during the initial incision
the surgeon views the penetration of the tissue by the
blade and the guard is disposed at the side of the blade
out of the line of view. For right-handed surgeons, where,
for example, the sclera of the eye above the cornea is
35 being cut in a counterclockwise direction, it is advantageous

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1 to locate the tip to one side of the blade whereas a left-
handed surgeon would make the incision in a clockwise
fashion and accordingly the tip should be disposed at the
other side of the blade. For this purpose, the scalpel
5 according to the present invention includes a set of guards
having those adapted, when positioned on the handle, locate
the tip to the one end side of the blade and guards adapted
to locate the tip to the other side of the blade. Color
coding of the guards is employed to aid the surgeon in
10 selection.

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1 Brief Description of the Drawings

These and other features and advantages of the present invention will become apparent as the same becomes better understood with reference to the specification, claims and
5 drawings wherein:

FIG. 1A is a top view of a scalpel according to the present invention for making incisions from left to right;

FIG. 1B is the scalpel according to the present invention similar to that of FIG. 1A for making incisions
10 particularly from right to left;

FIG. 2 is an end view of the scalpel according to the present invention;

FIG. 3 is a top assembly view of the guard for the scalpel of FIG. 1A;

15 FIG. 4 is a section view of the guard taken along line 4-4 of FIG. 3;

FIG. 5 is a perspective assembly view of the scalpel according to the present invention showing the coupling between the guard and handle; and

20 FIG. 6 is an end view of the scalpel of FIG. 1A illustrating the coupling and decoupling of the guard.

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1 Detailed Description

Turning to the drawings, FIGS. 1A and 1B illustrate a scalpel 10 according to the present invention. Scalpel 10 is adapted to make an initial incision of a nominal first depth and is transformable to make an incision of a second, greater depth. The scalpel of FIG. 1A is particularly adapted to make the aforesaid initial incision of nominal depth in a direction from left to right whereas the scalpel of FIG. 1B is adapted to make the initial incision of nominal depth in a direction from right to left. For example, given the relative position of the surgeon's hand to the patient, the scalpel of FIG. 1A may be particularly adapted for use in the right hand whereas the scalpel of FIG. 1B may be adapted for use in the left hand. Dependent upon the surgeon's preference, i.e., right-handedness or left-handedness, the scalpel of FIG. 1A may be preferred by a right-handed surgeon whereas the scalpel of FIG. 1B may be preferred by a left-handed surgeon. Since the embodiments of the scalpel represented by FIGS. 1A and 1B are functionally and structurally similar, the following description will be primarily directed to the embodiment of FIG. 1A.

The scalpel 10 includes a handle 12 having at one end a conical mount 14 which tapers downwardly from the handle 12 to a smaller diameter base 16. An annular rim 15 defines a transition surface between the diameter of the handle and that of the base 16. Secured to the base 16 is a blade 18 of sharpened surgical steel having, as shown in FIG. 5, a point 20 for penetrating tissue and a cutting edge 22.

To control the depth of cut of the blade 18, the blade 18 is so positioned and secured to the handle such that the point 20 is at a predetermined distance from the base 16 defining a depth of cut A, as shown in FIGS. 1A and 1B, which may or may not be preset to a precise,

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1 predetermined depth. For example, when the scalpel 10 is
adapted for cataract surgery, depth of cut A may be
approximately 1000 microns since the tissue of the sclera
being cut typically has a thickness of between 300-700
5 microns.

During the incision, the blade is inserted through
the tissue to complete the intraocular incision.

As best shown in FIG. 3, the handle 12 may include a
circumferential indentation 28 to better accommodate the
10 surgeon's grip of the scalpel. Proximate the mount 14 and
indentation 28, the handle 12 also includes a rectangular,
outwardly projecting key 30. Key 30 includes radial forward
and rear walls 32 and 34, respectively, and side walls 36.
The key 30 is aligned with respect to the blade 18 so that
15 the surgeon can, by feel of the key 30, determine the
orientation of the blade and its edge 22. According to
the embodiment shown, the longitudinal axis for the key 30
is aligned with the cutting edge 22. The key 30 also
enhances the surgeon's grip of the scalpel and more
20 particularly its handle 12 in that the key 30 may
conveniently be gripped between the thumb and the forefinger.

To cooperate with the handle 12, the scalpel 10 further
includes a guard 38 and means for coupling the guard 38
with, for example, a bayonet-type connection, to the handle
25 12 to limit the depth of cut of the blade to a predetermined,
lesser depth. As shown in FIG. 1A, this lesser depth of
cut is represented by depth B. In certain surgical
procedures, such as cataract surgery, it has been found
advantageous to make an initial incision at the desired
30 location and along the desired line at a nominal, first
depth, represented by depth B which may be 300 - 400 microns.
Since relatively little tissue is being cut a smooth,
precise, continuous initial incision can be made by the
surgeon.

35 As shown in the drawings, a bayonet-type connection

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1 38 is provided between the guard 38 and handle 12. The guard
38 includes a sleeve 40 having an inside diameter adapted
to closely fit over the handle 12. The sleeve 40 includes
a longitudinal extending slot 42 having an arc length
5 slightly greater than that represented by the span between
the side walls 36 of the key 30. The guard 38, and more
particularly its sleeve 40, can be passed over the handle
12 as shown in FIGS. 3 and 5 with the slot 42 accommodating
the key 30. The guard 38 can be fashioned from a plastic,
10 metal or any other suitable materials. When the guard 38
is positioned over the handle 12, the sleeve 40 resiliently
expands providing an interference fit between the guard 38
and handle 12 to prevent the guard 38 from inadvertently
rotating relative to the handle 12.

15 As shown in FIGS. 3 and 5, the sleeve 40 also includes
a rectangular pocket 44 opening into the slot 41 and defined
by first and second walls 46 and 48 and bottom wall 50.
The first and second walls 46 and 48 are spaced apart so
as to closely receive the key 30 when the guard 24 is
20 passed over the handle 12 and rotated to thereby position
at least a portion of the key 30 in the pocket 44. The
positioning of the key 30 within the pocket 44 such that
the first and second walls 46 and 48 abut the forward and
rear walls 32 and 34 to confine the key 30 within the
25 pocket 44 precisely axially positions and firmly holds the
guard 24 on the handle 12. A tab 52 projects from the
bottom wall 50 to contact a side wall 36 to rotationally
limit and align the guard and more particularly the sleeve
40 on the handle 12 for purposes which will hereinafter
30 become evident.

Projecting longitudinally from the sleeve 40, the
guard 38 further includes an arm 54 which is angled to
follow the contour of the conical mount 14 and may be
somewhat arcuate in cross-section. At the junction between
35 the arm 54 and sleeve 40, the arm 54 is somewhat thicker

-10-

1 than the sleeve 40 to define an arcuate stop 56 adapted to
abut the annular rim 15 of the handle 12 when the guard 38
is positioned over the handle 12 to initially limit the
axial positioning of the guard on the handle. Arm 54
5 tapers and thins as it extends outwardly from the stop 56
defining converging side margins 58 and 60 for the arm 54.
Remote from the sleeve 40 the side margins terminate at a
tip 62. Tip 62 is defined by a face 64 which is adapted
to, when the guard 24 is disposed on the handle 10, lie
10 parallel and adjacent the blade 18 and to substantially
overshadow the blade 18. As best shown in FIGS. 2 and 4,
the face 64 is aligned substantially with side margin 60.
The face 64 is somewhat triangular having a truncated apex
66 adapted to be positioned relative to the blade point 20
15 to define the nominal depth of cut B as illustrated in
FIG. 1. To so define the face 64 the tip 62 includes a
surface 68 remote from the apex 66 and lying orthogonal to
the face 64 fashioning the transition between the arcuate
arm 54 and its tip 62. On its outer surface the tip 62
20 may taper or neck down to define an outer wall 70 for the
tip 62 which extends from a rounded end 72 which engages
the tissue being severed and intersects the apex 66 to a
ridge 74 forming the transition from the outer wall 70 to
the surface defined by the arm 54. For purposes which
25 will hereinafter become evident and with reference to
FIGS. 2 and 4 through 6, a shallow notch 76 is formed in
the face 64 and side margins 60. To position a guard 38
on the handle 10, the guard is aligned with the handle
such that the key 30 is positioned to register with the
30 slot 42 of the sleeve 40, as shown in FIG. 5. The guard
is passed over the handle 12, the sleeve resiliently
expanding a small amount to accommodate the handle 12 and
the key 30 passing into the slot 42. When the guard 38 is
at the approximate desired axial position the stop 56
35 engages the rim 15. As shown in FIG. 6, as the guard is

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1 initially passed on to the handle 12, the notch 76
accommodates the blade 18 without interference. Thereafter,
the guard is rotated in a counterclockwise direction to
receive at least a portion of the key 30 within the pocket
5 44. The tab 52 is constructed to engage by side wall 36
to precisely limit the rotation of the guard 38 the desired
amount. In this position, as shown in FIG. 1A, the first
wall 46 abuts key rear wall 34 and the second wall 48
abuts key forward wall 32 thereby precisely locating the
10 guard 38 on the handle 12. During manufacture, the first
and second walls 46 and 48 and key rear and side walls 34
and 36 are disposed to achieve the desired relative position
of the guard 38 on the handle 12. With the guard so
positioned, the surgeon can make the initial, nominal
15 incision at depth B along the desired line. Since a
relatively small amount of tissue is being cut a smooth,
continuous incision can easily be made. Once the initial
incision has been made at nominal depth B, the guard 38 is
rotated clockwise (FIG. 5) to release the key 30 from the
20 pocket 44 and the guard 38 is removed from the handle 12.
The surgeon then, using the initial nominal incision as a
guide, inserts the blade 18 at an angle into the nominal
incision and using that incision as a guide retraces the
cut beveled, completing the intraocular incision.

25 By this procedure, it can be appreciated that by
using the initial cut as a guide a smooth, continuous,
intraocular, beveled incision can be made which provides
for a watertight closure and reduces astigmatism.
Furthermore, the initial cutting at nominal depth and
30 finished incision are accomplished by using one scalpel,
thereby achieving a cost savings.

For the scalpel 10 of FIG. 1B, the guard 38 is passed
over the handle 12 and is rotated clockwise locking the
guard to the handle 12 and its key 30. As illustrated,
35 the guard for this embodiment can be a mirror image of

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1 that shown in FIG. 1A for use with the same handle. Guard
38 is rotated counterclockwise for removal from the handle.

To aid surgeons in selecting which guard 38 to select,
i.e., the FIG. 1A or FIG. 1B embodiment, the guards may be
5 color coded. One color for the FIG. 1A embodiment and
another color for the FIG. 1B embodiment. Further, the
guards can be made to define different depths of cut B as
desired.

While I have shown and described certain embodiments
10 of the present invention, it is to be understood that it
is subject to many modifications without departing from
the spirit and scope of the claims as set forth herein.
For example, the key could be disposed on the guard and a
cooperative structure such as a J-slot could be fashioned
15 on the handle.

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1 WHAT IS CLAIMED IS:

1. A scalpel comprising:

a handle having at one end a cutting blade;
a guard including a tip; and

5 means for detachably coupling the guard to the handle, the coupling means including means for locating the guard at a predetermined position on the handle whereat the tip is disposed proximate the blade and the blade projects past the tip a predetermined amount defining a
10 depth of cut.

2. The scalpel of claim 1 wherein the handle includes a key, the coupling and locating means including means on the guard for receiving the key and defining the
15 predetermined position.

3. The scalpel of claim 2 wherein the key is a rectangular protuberance.

20 4. The scalpel of claim 3 wherein the rectangular protuberance is longitudinally in line with the blade thereby enabling the surgeon to determine the positioning of the blade by feel of the protuberance.

25 5. The scalpel of claim 3 wherein the receiving means includes a pocket to closely receive the rectangular protuberance when the guard is coupled to the handle.

30 6. The scalpel of claim 3 wherein the guard includes a sleeve portion adapted to be received over the handle, the sleeve portion including a longitudinal slot to pass the key and a pocket opening to the slot to closely receive the key and removably couple the guard to the handle upon relative rotation of the guard.

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1 7. The scalpel of claim 6 wherein the pocket includes
a tab to engage the key when the guard is rotated to
precisely limit said rotation.

5 8. The scalpel of claim 1 wherein the guard includes
a sleeve portion adapted to be removably coupled to the
handle at a predetermined position, an arm projecting from
the sleeve portion to a tip disposed at one side of the
blade, said blade exposed from the tip a predetermined
10 amount defining said depth of cut.

15 9. The scalpel of claim 8 wherein said blade is
exposed to define a depth of cut in the range of 300 to
400 microns.

15 10. A scalpel comprising:
a handle having at one end a mount terminating
at a base;
a blade disposed at the mount and defining a
20 first depth of cut in relation to the base;
a guard including at one end a tip; and
means for removably attaching the guard to the
handle, the attaching means including a bayonet-type
connection between the guard and handle defined by a key
25 and a slot, said key and slot positioned to locate the tip
in relation to the blade such that the blade projects past
the tip a predetermined amount defining a second depth of
cut.

30 11. The scalpel of claim 10 wherein the first depth
of cut is fixed at a first, predetermined depth of cut.

12. The scalpel of claim 11 wherein the first
predetermined depth of cut is about 3000-5000 microns.

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1 13. The scalpel of claim 10 wherein the predetermined
second depth of cut is less than the first.

5 14. The scalpel of claim 13 wherein the predetermined
second depth of cut is in the range of 300 - 400 microns.

10 15. The scalpel of claim 10 wherein the guard includes
a sleeve adapted to pass over the handle and the attaching
means includes a key on the handle and a slot in the sleeve,
passing of the sleeve over the handle causing the key to
register with the slot, said sleeve further including a
pocket opening to the slot, rotation of the sleeve locating
the key in the slot to locate the guard so that said blade
projects past the tip the predetermined second depth of cut.

15 16. The scalpel of claim 15 wherein the guard includes
an arm projecting from the sleeve to the tip disposed
adjacent and to one side of the blade.

20 17. The scalpel of claim 16 wherein the tip includes
a notch to accommodate the blade when the sleeve is passed
over the handle.

25 18. A scalpel comprising:
a handle having at one end a blade defining a
first depth of cut;
a set of at least two guards each including a
sleeve to pass over the handle, at least one of said guards
including an arm having a tip adapted to be disposed to
30 one side of the blade and at least one other guard including
an arm having a tip adapted to be disposed to the other
side of the blade;

means for distinguishing said one guard from the
other guard; and

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1 means for detachably coupling a selected guard
to the handle to locate the tip such that the blade projects
past the tip a predetermined amount defining a second
depth of cut.

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19. The scalpel of claim 18 wherein the distinguishing
means includes color coding.

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FIG. 1A.

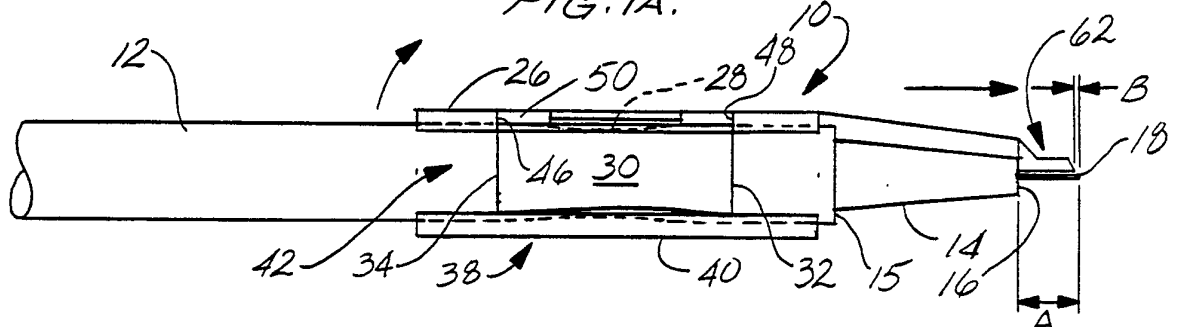


FIG. 1B.

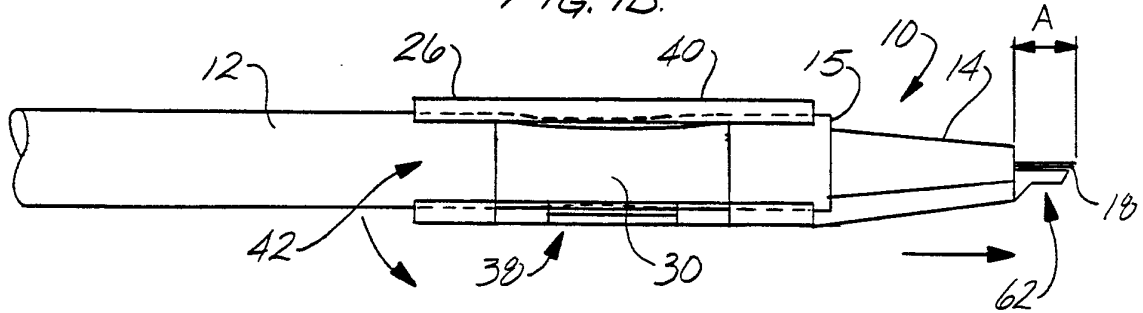


FIG. 2.

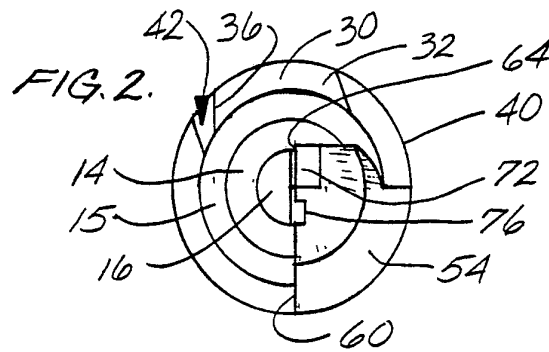


FIG. 3.

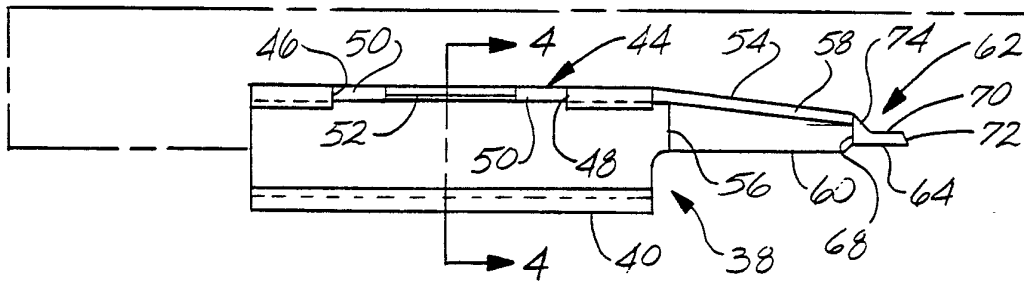
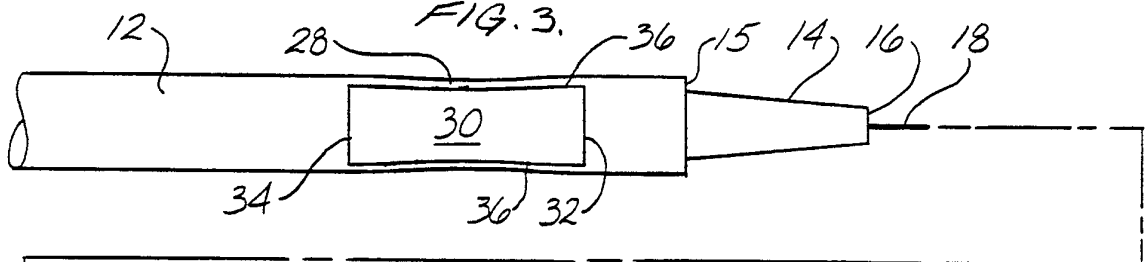
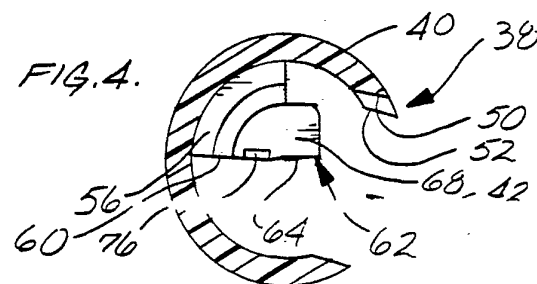
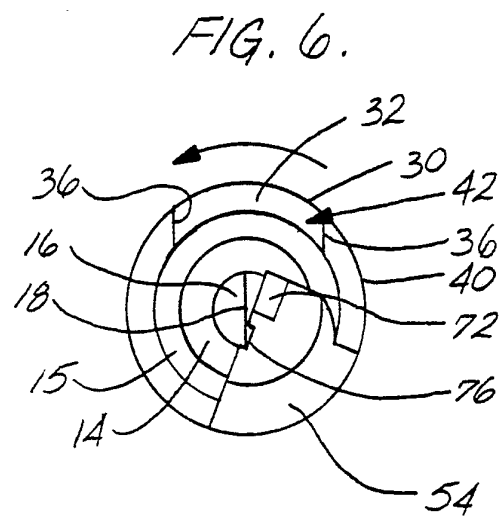
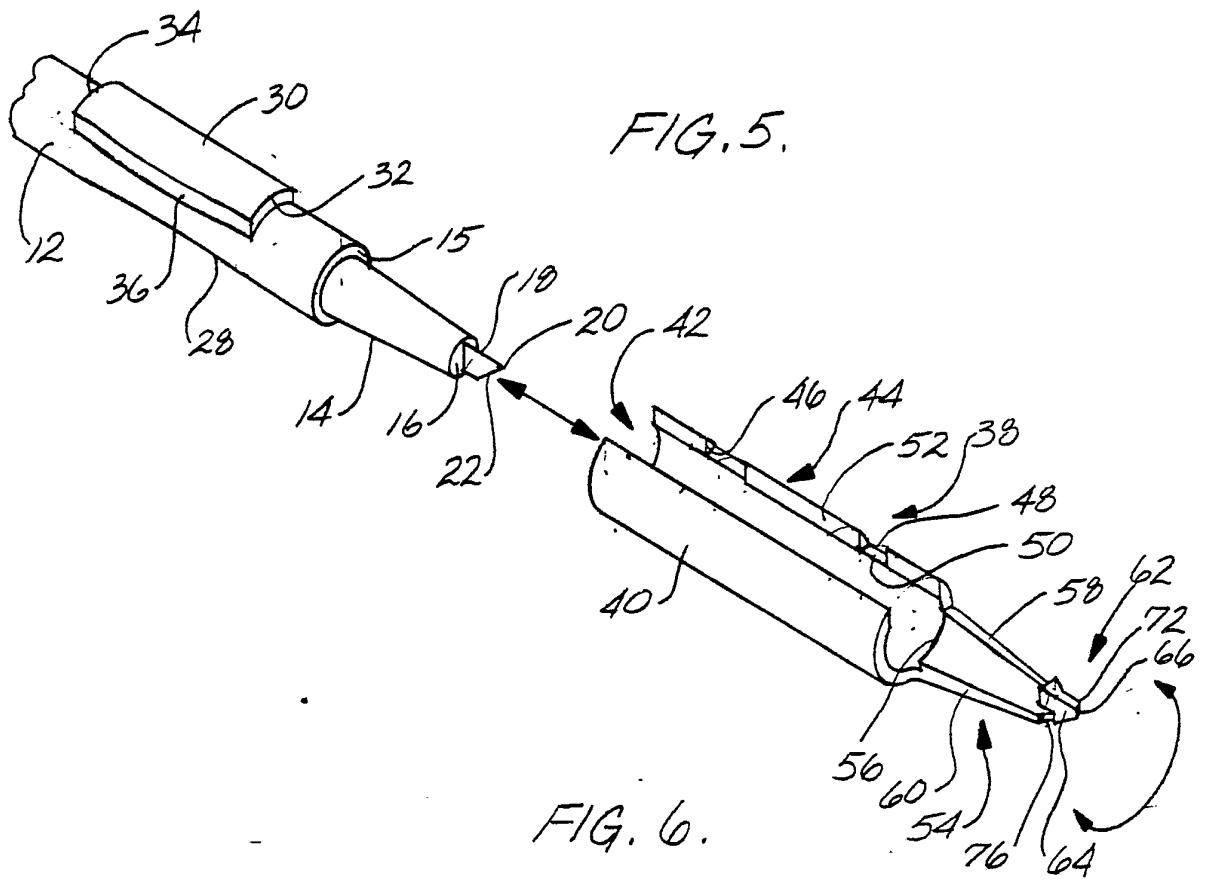


FIG. 4.





INTERNATIONAL SEARCH REPORT

International Application No **PCT/US86/01924**

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³		
According to International Patent Classification (IPC) or to both National Classification and IPC IPC(4): A61B 17/32, A61B 17/14, B26B 29/00 U.S. CL. 128/305, 317; 30/293		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁴		
Classification System	Classification Symbols	
U.S.	123/305, 317 30/293, 294, 289, 300	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category ⁶	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
X Y	UK, A, 2,113,550 A (KEMP) 10 August 1983 See the entire document.	1,2,8-11, 13,15
Y,P	US, A, 4,569,133 (SCHMIDT) 11 February 1986 See the entire document.	3-7,12,14 16,17
Y	UK, A, 218,942 (SOUTTAR) 17 July 1924 See the entire document.	18,19
A,P	US, A, 4,552,146 (JENSEN ET AL) 12 November 1985 See the entire document.	1,10
A	US, A, 3,945,117 (BEAVER) 23 March 1976 See the entire document.	1,10
A	US, A, 3,457,643 (HILL) 29 July 1969 See the entire document.	1,10
<p>⁶ Special categories of cited documents: ¹⁵</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search ²	Date of Mailing of this International Search Report ³	
16 September 1986	22 DEC 1986	
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ISA/US	R. A. Smith	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No ¹⁸
A	US, A, 4,520,815 (MARINOFF) 04 June 1985 See the entire document.	1, 10
A	US, A, 4,516,575 (GERHARD ET AL) 14 May 1985 See the entire document.	1, 10
A	US, A, 4,473,076 (WILLIAMS ET AL) 25 September 1984 See the entire document.	1, 10
A	US, A, 4,499,898 (KNEPSHIELD ET AL) 19 February 1985 See the entire document.	1, 10
A	US, A, 4,534,348 (FEDOROV ET AL) 13 August 1985 See the entire document.	1, 10
A	US, A, 4,073,056 (SCHAEFFER ET AL) 14 February 1978 See the entire document.	1, 10
A	US, A, 4,324,044 (SHAHINIAN, JR.) 13 April 1982 See the entire document.	1, 10
A	FR, A, 2,487,188 (MALAGUTI) 29 January 1982 See the entire document.	1, 10
A	SU, A, PCT/SU80/00156 (NIKOLAEVICH ET AL) 18 March 1982 See the entire document.	1, 10