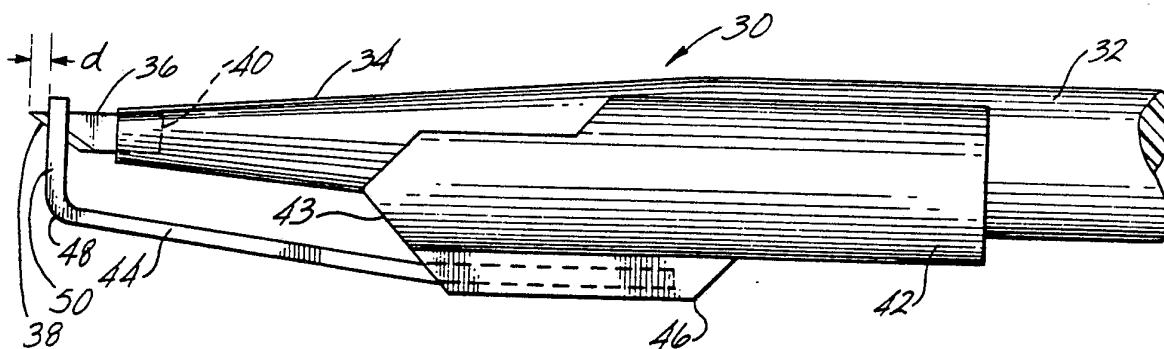




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(21) International Application Number: PCT/US83/01575 (22) International Filing Date: 5 October 1983 (05.10.83) (71)(72) Applicant and Inventor: JENSEN, Ronald, P. [US/US]; 1612 Golf Club Drive, Glendale, CA 91206 (US). (74) Agent: CARNEY, Hayden, A.; Christie, Parker & Hale, P.O. Box 7068, Pasadena, CA 91109-7068 (US). (81) Designated States: AT, AT (European patent), AU, BE (European patent), BR, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE, DE (European patent), DK, FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), HU, JP, KP, LK, LU, LU (European patent), MC, MG, MR (OAPI patent), MW, NL, NL (European patent), NO, RO, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US.		Published <i>With international search report.</i>

(54) Title: SCALPEL WITH A FIXED DEPTH OF CUT



(57) Abstract

A disposable scalpel (30) having a fixed depth of cut and particularly adapted for radial keratotomy which has a handle (32) with a blade (36) attached to one end. Fixed to the handle (32) is a sleeve (42) which includes an outwardly projecting mount (46) adapted to hold and support a foot (44). The mount (46) in cooperation with the handle (32) and sleeve (42) enables the surgeon to securely and comfortably grasp the scalpel (30). To determine the depth of cut, the foot (44) projects from the mount (46) to define a bifurcated guard (50) which straddles the blade (36). During surgery, the guard (50) is adapted to bear against the cornea to limit the depth to which the blade (36) cuts. The blade (36) projects through the guard (50) to define the depth of cut. By accurately fixing the sleeve (42) and thereby the foot (44) to the handle (32) during manufacture, a precise depth of cut can be provided for the scalpel (30). Also provided is a kit of scalpel sets, the scalpels of each set being the same depth of cut and depth of cut varying from set to set. The number of scalpels in each set is determined by the normal distribution of the probability that a particular depth of cut will be required (Fig. 8).

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SCALPEL WITH A FIXED DEPTH OF CUT

Field of the Invention

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This invention relates to scalpels which include means to control the depth of cut. More particularly, this invention relates to scalpels for use in radial keratotomy.

Background of the Invention

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In certain surgical procedures, it is necessary for the surgeon to determine and accurately control the depth to which he or she cuts with a scalpel. A specific example is the surgical procedure known as radial keratotomy. This procedure corrects myopia (nearsightedness) by altering the curvature of the cornea of the eye. The curvature is altered by making a series of radial incisions in, but not through, the cornea itself.

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To have predictable and favorable results, the depth of cut into the cornea must be accurately determined and controlled. The incisions must have sufficient depth, usually just greater than three-quarters of the depth of the cornea, but should not

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1 penetrate the cornea itself. Penetration of the
cornea would release fluid from the anterior chamber
of the eye, increase the likelihood of infection,
and detract from the predictability of the results of
5 the procedure.

In controlling the depth of cut, it is to be
noted that the thickness of the cornea varies from
patient to patient and accordingly, must be accurately
determined by known means prior to surgery. Once the
10 thickness of the cornea has been accurately determined,
the appropriate depth of cut can be selected.

To accommodate the varying thicknesses of corneas,
and accordingly, the desired depth of cut, it has been
known to provide for adjustable scalpels. However,
15 adjustable scalpels have several drawbacks. One
drawback relates to the predictability of the depth of
the cut. To set the depth of cut, the surgeon must,
by hand and using a scale or a gauge, adjust depth of
cut of the scalpel. One type of adjustable scalpel
20 includes a blade coupled with an adjustable micrometer-
like knob on the handle. Another type uses a depth
gauge separate from the scalpel and provides for
adjustment of the depth of cut by movement of a
guard relative to the scalpel blade cutting edge, the
25 guard being positionally fixed to the scalpel handle
by a thumbscrew after determination of the desired
cut depth.

As can be appreciated, the setting of depth of
cut either by using the adjustment knob or by com-
30 parison with the depth gauge does not always produce
accurate, predictable results, particularly results
having an accuracy to within 10 microns, i.e., $\pm$
0.010 mm. In many cases, the gauges are not accurate.

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1 Another problem of scalpels having an adjustable
depth of cut occurs in setting the depth of cut after
the desired adjustment has been ascertained by use of
a gauge. The fixing of the adjustable member may
5 alter the setting, thereby again detracting from the
accuracy of the depth of cut setting. Still another
drawback is that adjustable scalpels tend to be expensive.
Yet another drawback is that reusable scalpels
must be sterilized and their blades tend to dull with
10 repeated use. Also, the adjustment can be disturbed
inadvertently in the course of the surgical procedure.

Summary of the Invention

15 There is, therefore, provided in the practice of
this invention a disposable scalpel particularly
adapted for radial keratotomy. The scalpel includes
a handle which mounts a blade at one end, the blade
having a suitable cutting edge. A sleeve is fixed to
20 the handle near its one end and includes an outwardly
projecting mount. The mount, in cooperation with the
handle and the sleeve, enables the surgeon to securely
and comfortably grip the scalpel between the index
finger, middle finger, and thumb, and with the cutting
25 edge consistently oriented in a proper position. To
control the depth of cut, a foot is provided. The
foot is preferably metallic to resist bending and
twisting which would effect the depth of cut and has
one end attached to the sleeve. Additionally, the
30 metallic foot can be made relatively narrow so as not
to interfere with the surgeons view while still resisting
deflection. From the sleeve, the foot projects
toward the blade to define, remote from the sleeve, a
bifurcated guard defined by a pair of arms which run
35 parallel to and straddle the blade cutting edge.

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1 During the surgical procedure, the arms are adapted
to bear against the cornea, the extension of the
cutting edge past the guard determining the depth of
cut. By accurately fixing the position of the sleeve
5 on the handle during manufacture of the scalpel, the
position of the guard relative to the cutting edge is
accurately preset, thereby accurately determining the
depth of cut to within 10 microns.

Also disclosed is a kit including a plurality of
10 sets of scalpels, all scalpels in a set having a
particular depth of cut and the depth of cut varying
from set to set within the range between 0.435mm to
0.755mm. The number of scalpels in any particular
set is determined by the normal population distribution
15 of the likelihood that any particular depth of cut
will be required. Accordingly, the sets corresponding
to rarely used depths of cuts will contain relatively
few scalpels whereas the sets corresponding to often
used sets of cut will contain more scalpels.

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SUBJECT



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1 Brief Description of the Drawings

These and other features and advantages of the present invention will be appreciated as the same becomes better understood by reference to the following details description of the presently preferred
5 embodiments when considered in connection with the accompanying drawings in which like reference numerals refer to like features and wherein:

FIG. 1 is a perspective side view of an adjustable
10 scalpel according to the prior art;

FIG. 2 is a side elevation view of a scalpel according to the present invention;

FIG. 3 is an enlarged side elevation view of the tip of the scalpel shown in FIG. 2;

15 FIG. 4 is a front end view of the scalpel shown in FIG. 2;

FIG. 5 is a partial top view of the scalpel shown in FIG. 2;

20 FIG. 6 is a partial side view of the scalpel as held in the hand;

FIG. 7 is a front end view of the scalpel as held in the hand; and

25 FIG. 8 is a graphical depiction of the distribution of the required depth of cut based upon empirical data with the ordinate representing depth of cut and the abscissa representing number of occurrences in which a particular depth of cut was required in a radial keratotomy procedure.

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1 Detailed Description

Turning to FIG. 1, a scalpel 10 according to the prior art is shown. The scalpel 10 has a handle 12 which may be fashioned from plastic or the like. At one end of the handle is fixed a blade 14 having a suitable cutting edge 16. The cutting edge 16 is adapted to make incisions into the cornea of the patient during the surgical procedure known as radial keratotomy.

10 To control the depth of cut of the scalpel 10, a sleeve 18 is adjustably mounted to the handle 12. As can be appreciated from FIG. 1, the sleeve 18 passes over the handle 12 and can be fixed relative thereto by a set screw 20. The sleeve 18 includes a foot 22 which projects toward the blade 14 to define a guard shown generally as 24. The guard 24 is bifurcated to define a pair of parallel arms 26 spaced apart by a gap 28, the arms 26 straddling and extending parallel to the blade and normal to the length of the scalpel handle at the anterior end of the scalpel. As can be seen, the blade cutting edge 16 extends through the gap 28 and past the arms 26. During radial keratotomy, the anterior surfaces of the arms 26 bear against the cornea to prevent the cutting edge 16 from cutting too deep into or penetrating the cornea.

25 By adjusting the position of sleeve 18 along the handle 12, the extent to which the cutting edge 16 protrudes through the gap 28 outwardly (anteriorly) of the guard 24 can be determined. The amount to which the cutting 16 protrudes past the guard 24 defines the depth of cut of the scalpel 10.

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1 One drawback of the prior art, adjustable
scalpel 10, involves the setting of the depth of cut.
To set the depth of cut, a separate depth gauge is used
to determine the position of the guard 29 relative to
5 the tip of the blade cutting edge 16. A surgeon or
technician is required to compare the depth of cut as
set on the scalpel 10 with the gauge and adjust the
position of the sleeve 18 accordingly. As can be
appreciated, the setting of the depth of cut is not
10 exact. Misperception, inaccuracy of the gauge, or
other factors noted above, either acting in combination
or acting independently, can detract from the overall
accuracy of the depth of cut setting. As discussed
above, an inaccurate setting of the depth of cut can
15 result in complete penetration of the cornea or an
improper depth of cut, thus causing the result of the
surgical procedure to be other than as desired. As
can be appreciated, it has been found that setting
the depth of cut to an accuracy within 10 microns
20 cannot be consistently accomplished.

To further detract from the accuracy of the
scalpel, the tightening of the set screw 20 may in
and of itself tend to alter the position of the
sleeve 18 along the handle 12 and thereby the location
25 of the arms 26 relative to the cutting edge 16. This
in turn, causes a deviation in the depth of the cut
setting. Furthermore, since the scalpel 10 is adapted
to be used repeatedly, the tightening of the set screw
20 may produce dimples in the handle 12. In setting
30 the depth of cut, the set screw 20 may tend to seek
an adjacent dimple thereby altering the position of
the sleeve 18 along the handle 12 and the setting of
the depth of cut.

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1 Turning to the FIGS. 2 through 5, a presently
preferred scalpel 30 according to the present
invention is shown. The scalpel 30 includes a handle
32 preferably molded from plastic or the like. The
5 handle 32 is cylindrical having a longitudinal axis
and having one end tapered to define a forward tip
34. Mounted to the tip 34 is a blade 36 having a
surgical cutting edge 38. To mount the blade 36, the
tip 34 is provided with an axial aperture 40 which
10 may mount the blade 36 by an interference fit.
Alternatively, the blade may be secured to the handle
by insert molding of the blade 36 into the handle 32
or the blade 36 may be bonded into the aperture 40
and handle 32 by a suitable glue. Accordingly, the
15 blade 36 is securely affixed to the handle 32 and is
prevented from moving axially and angularly relative
to the handle 32.

To set a depth of cut, the scalpel 30 includes a
sleeve 42, preferably of molded plastic, adapted to
20 be fixed to the handle 32 near the tip 34. The
sleeve 42 is semi-cylindrical having a forward end 43
and having an internal diameter adapted to mate with
the outside diameter of the handle 32. During the
manufacture of the scalpel 30, as describe below,
25 the sleeve 42 is precisely positioned along the
handle 32 and is thereafter fixed to the handle 32 by
sonic welding, by a suitable adhesive, or by other
means. Accordingly, the sleeve 42 once fixed to the
handle 32 is prevented from moving relative thereto.

30 The sleeve 42 holds and supports a gauge member
or foot 44 which preferably is fashioned from metal
to prevent deflection such as by bending and twisting
during the surgical procedure. Deflection of the
foot 44 would tend to unpredictably alter the depth
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1 of cut. Additionally, by being fashioned from metal,
the foot 44 can be made relatively narrow so as not
to obscure the surgeon's vision.

5 To hold the foot 44, and for other purposes
which will hereinafter become evident, the sleeve 42
includes a radially outwardly projecting mount 46.
As shown in the drawings, the mount 42 is preferably
rectangular and extends longitudinally along the
10 sleeve 42 at approximately the circumferential
midpoint from the forward end 43 to a point repre-
senting approximately one-half the longitudinal
length of the sleeve 42. It is to be understood,
however, that the mount 46 can have other configura-
tions and orientations suitable for operation of the
15 scalpel 30 as herein set forth.

To hold the foot 44, the foot 44 may be insert
molded into the mount 46, or the mount 46 may be
provided with a receptacle to receive the foot which
is thereafter bonded into the receptacle by a suitable
20 glue or the like. Accordingly, the foot 44 and sleeve
42 are positioned and fixed along the handle 32 as a
unit.

The foot 44 projects from the mount 46 substan-
tially parallel to the taper of the handle tip 34 to
25 a point spaced posteriorly from but near the tip of
the blade cutting edge 38. At the aforementioned
point, the foot 44 is bent to define an elbow 48 and,
as shown in the drawings, particularly at FIG. 3, an
upwardly extending guard 50. The angle of the bend
30 of the elbow 48 is such that the guard 50 is substan-
tially transverse to the longitudinal axis of the
handle 32.

During a radial keratotomy procedure, the surgeon
places and maintains the guard 50 against the cornea
35 to, as described below, produce the desired incision
having the proper depth of cut.



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1 To accommodate the blade 36 for making the
incisions the guard 50 is bifurcated to define a pair
of parallel arms 52 spaced apart by a gap 54. The
arms extend to either side of or "straddle" and are
5 positioned transversely of the blade cutting edge 38.
The blade 36, and more particularly the cutting edge
38, extends through the guard 50, and more particularly
the gap 54, to define the depth of cut shown as "d" in
FIG. 3. The arms 52 have a length adequate to project
10 past the blade 36 so that the cutting edge 38 can
freely pass through the gap 54.

As can be appreciated from FIGS. 4 and 5, the
longitudinal axis of the foot 44 lies in the plane
defined by the cutting edge 38. Additionally, the
15 mount 46 is oriented to have its longitudinal axis
coplanar with the axis of the foot 44. Therefore, the
mount 46 has a longitudinal axis coplanar with the
cutting edge 38.

To set the depth of cut "d" for the scalpel 30,
20 the sleeve 42 is precisely positioned along the handle
32 such that the relative position of the guard 50 to
the cutting edge 38 establishes the depth of cut "d" to
within 10 microns of the selected setting. For radial
keratotomy, the selected depth of cut typically falls
25 between 0.435mm and 0.755mm. Since the positioning
of the sleeve 42 along the handle 32 is done during
manufacture rather than in the hospital operating
room or the like, precise positioning to within 10
microns can be obtained. After the sleeve 42 has
30 been located at the selected position, it is fixed to
the handle 32 by sonic welding, glue, or the like.

As can be appreciated, the scalpel 30 is relatively
inexpensive since both the handle 32 and sleeve 42 are
molded from plastic. The only metallic parts are the
35 foot and blade. Due to the inexpensive nature of the
scalpel 30, it is disposable. Since the scalpel 30

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1 is disposable, the problem of dull blades encountered
by repeated use of scalpels, such as the adjustable
scalpel 10, is not encountered. Furthermore, since
the setting of the sleeve on the handle is done at
5 the factory, the depth of cut "d" can be accurately
determined. As an added advantage, the scalpel 30
can be sterilized and prepackaged, dispensing with
the need for sterilization.

Turning to FIGS. 6 and 7, a further advantage of
10 scalpel 30 is shown. In holding the scalpel 30, the
surgeon grasps it between the index and middle fingers
and the thumb. With prior art scalpels having a
cylindrical shape at the point of grasp, the fingers
and thumb could only support the scalpel at basically
15 three points around its circumference. Accordingly,
the scalpel would be subject to rotation within the
surgeons hand which, in turn, disorients the blade.
Furthermore, when picking up a cylindrical scalpel,
the surgeon cannot determine by feel in which direc-
20 tion the cutting edge is oriented. By providing the
sleeve 42 with the mount 46, it has been found that
the scalpel 30 can be more securely and comfortably
held and that the direction of orientation of the
cutting edge 38 can easily be determined by feel when
25 the scalpel is picked up. As shown in FIG. 7, the
mount 46, sleeve 42, and handle 32 cooperate to
approximate a triangular periphery which securely and
comfortably mates with the index and middle finger
and thumb during the normal grasp of the scalpel 30.
30 The mount also provides means for easily determining
by feel the direction of cut by virtue of having its
longitudinal axis oriented coplanar with the cutting
edge 38.

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1 While individual pre-set scalpels may be separately
provided, the present invention also contemplates
providing a number of sets of scalpels 30 in a kit,
the scalpels of each set having the same depth of cut
5 and the depth of cut varying from set to set. The
kit may include the same number of scalpels in each
set. However, this would not be cost effective since
some required depths of cuts are rarely encountered
whereas others are frequently used simply due to the
10 normal distribution of variances of cornea thicknesses
and other pertinent factors determination of desired
depth of cut.

To make the kit of scalpels 30 more cost effective,
the number of scalpels provided in each set is based
15 upon the probability that a particular depth of
cut will be required. It has been found, based upon
empirical data from 533 cases that due to variations
in the thicknesses of corneas from patient to patient
and other pertinent factors, the probable depth of
20 cut varies from between 0.435mm and 0.755mm. It has
further been found that the population distribution
of required depths of cut is not random, but approxi-
mates a Gaussian or normal distribution as shown in
FIG. 8. For example, for any particular patient, the
25 probability or likelihood that the required depth of
cut will be 0.60mm is extremely more likely than that
the required depth of cut will be 0.45mm.

Therefore, the kit of scalpels, according to the
present invention, will contain sets of scalpels,
30 all of the scalpels of each set having a particular
depth of cut and the number of scalpels in any one
set being determined by the probability that that
particular depth of cut will be required. In other
words, the number of scalpels in any particular set
35 in the kit is based, approximately the probability
distribution of required use.

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1 The preceding description sets forth the pre-
 sently preferred embodiment of this invention and the
 presently known best mode of practicing this invention.
 That description is not exhaustive of all forms and
5 modes of practicing the invention. Workers skilled
 in the art to which the invention pertains will
 understand that the invention can be differently
 embodied or practiced without departing from, and
 while still relying upon, the essential aspects of
10 this invention.

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1 WHAT IS CLAIMED IS:

1. A scalpel for use in radial keratotomy comprising:

5 a handle (32) having mounted at one end thereof a blade (36) having a cutting edge (38) and a tip;

10 a sleeve (42) fixed to the handle (32) near the one end, the sleeve (42) including an outwardly projecting mount (46) disposed to stabilize the grip of the scalpel in the hand between the index, middle finger, and thumb; and

15 a foot (44) having one end fixedly received and supported by the mount (46) and a bifurcated guard (50) at other end adapted to straddle the blade (36) a selected distance (d) posteriorly of the blade tip, the location of the sleeve on the handle (32) determining the distance the blade (36) projects anteriorly from the guard (50) and thereby the depth of cut.

20 2. A scalpel as set forth in Claim 1 wherein the sleeve (42) is fixed to the handle (32) such that the blade (36) projects outwardly from the guard (50) to define a depth of cut in the range of from 0.400mm to 0.800mm.

25 3. The scalpel of Claim 1 wherein the sleeve (42) is cylindrical and is adapted to mate with and be fixed to the handle (32), the mount (46) being generally rectangular and projecting outwardly from the sleeve (42).

30 4. The scalpel of Claim 1 wherein the mount (46) is oriented in a selected relation relative to the blade (36), the positioning of the mount (46) by feel within the hand determining the orientation of the blade (36) in use.

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1 5. The scalpel of Claim 4 wherein the mount (46)
has a longitudinal axis arranged coplanar with the
blade (36).

5 6. The scalpel of Claim 1 wherein the handle (32)
and sleeve (42) are fabricated of a synthetic resin
plastic material.

10 7. A scalpel for making a surgical cut of
predetermined depth comprising:

an elongate handle (32) having mounted to
one end thereof a blade (36) extending from the
handle (32) parallel to the length of the handle
(32), the blade (36) having a cutting edge (38) and a
15 tip; and

a cut depth gauge member (44) fixed to the
handle (32) adjacent the one end thereof posteriorly
of the blade (36) and defining a pair of spaced gauge
arms (52) disposed on opposite sides of the blade (36)
20 and extending transversely of the blade cutting edge
(38) and substantially normal to the length of the
handle (32), the gauge arms (50) having substantially
coplanar anterior surfaces spaced a selected distance
(d) posteriorly of the blade tip which defines a
25 predetermined maximum depth of cut which can be
made by the blade (36) during use of the scalpel (30).

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- 1 8. A kit of scalpels (30) for performing radial
keratotomy, the kit comprising:
 a number of sets of scalpels (30), each scalpel
having,
5 a handle (32) having a blade (36)
 afixed to one end,
 a sleeve (42) fixed to the handle (32),
 the sleeve (42) mounting a foot (44) adapted
 to project from the sleeve (42) and having a
10 bifurcating end (50) straddling the blade (36),
 the position of the sleeve (42) on the
 handle (32) determining the relative position
 of the bifurcated end (50) to the blade (36)
 and thereby the depth of cut,
15 each set of scalpels (30) having a different
 depth of cut and the number of scalpels (30) in each
 set for any particular depth of cut determined by the
 probability that the particular depth of cut.
20 9. The kit of Claim 8 wherein the depths of cut
 of the scalpel (30) sets vary from 0.400mm to 0.800mm.
 10. The kit of Claim 9 wherein the scalpel (30)
25 sets vary in depth of cut from 0.435mm to 0.755mm in
 10mm increments.
 11. The kit of Claim 8 wherein the sets of
30 scalpels (30) vary incrementally in depth of cut from
 0.400mm to 0.800mm and the number of scalpels in each
 set is determined by a normal distribution curve
 descriptive of the probability of use.
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1 12. A kit of scalpels (30) useful for performing
radical keratotomy procedures comprising:

 a selected number of sets of scalpels (30),
each scalpel having

5 a handle (32) housing a blade (36)
affixed to one end thereof and projecting
therefrom to a blade tip, and

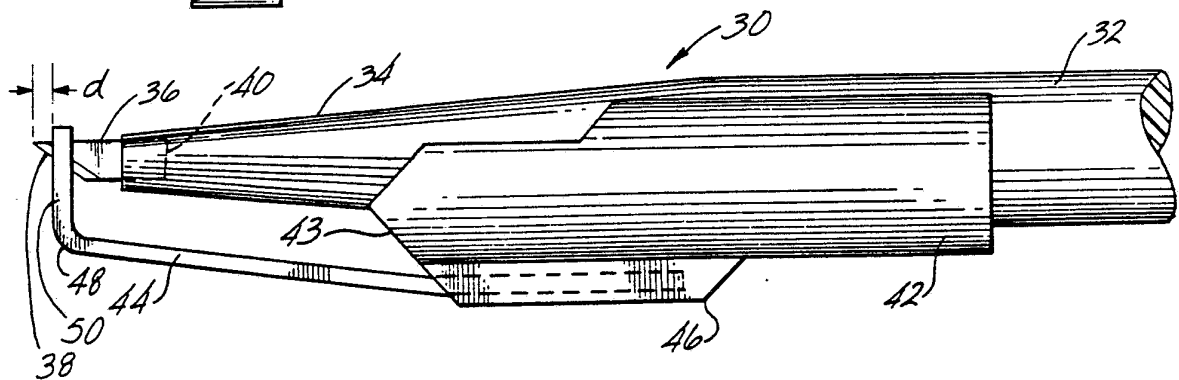
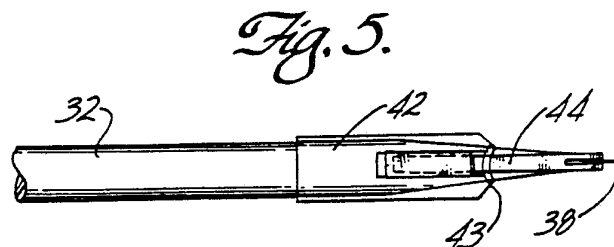
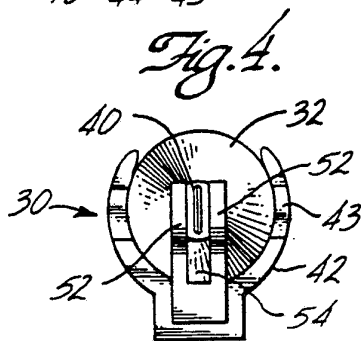
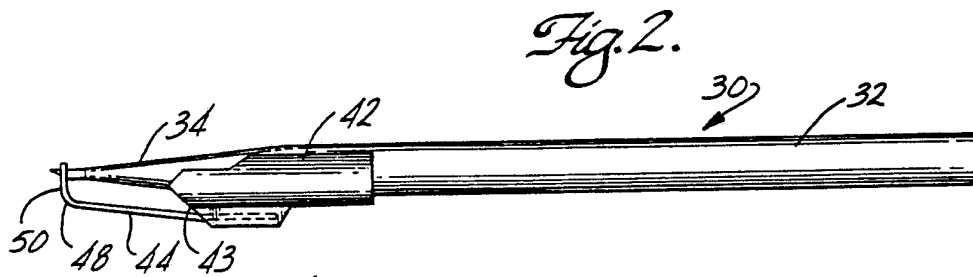
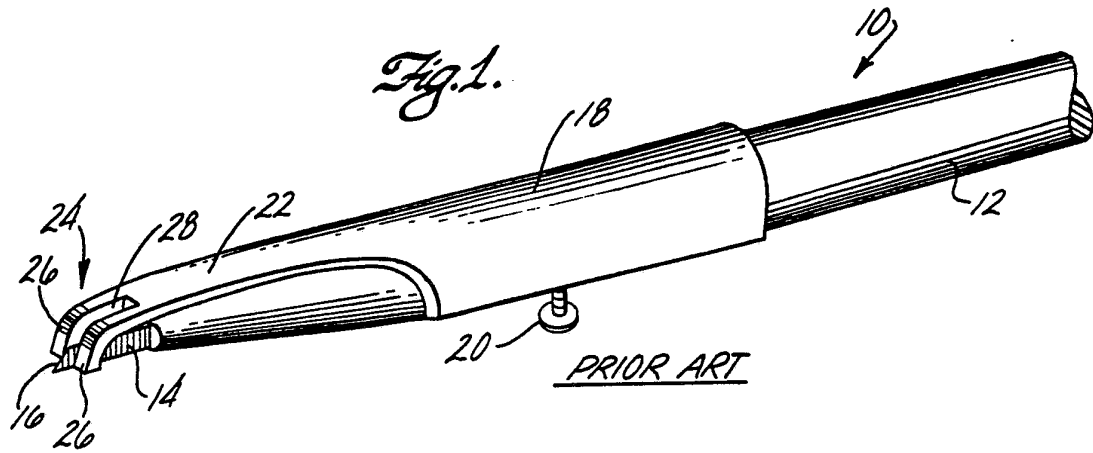
 a gauge member (44) fixed to the handle
(32) and cooperating with the blade (36) to
10 define a predetermined distance (d) of pro-
jection of the blade tip anteriorly of the
gauge member (44) relative to the handle
(32) whereby the gauge member (44) defines a
maximum depth of cut which can be made by

15 the scalpel (30) in use thereof,

 all scalpels (30) in each set having a
common blade tip projection distance (d),

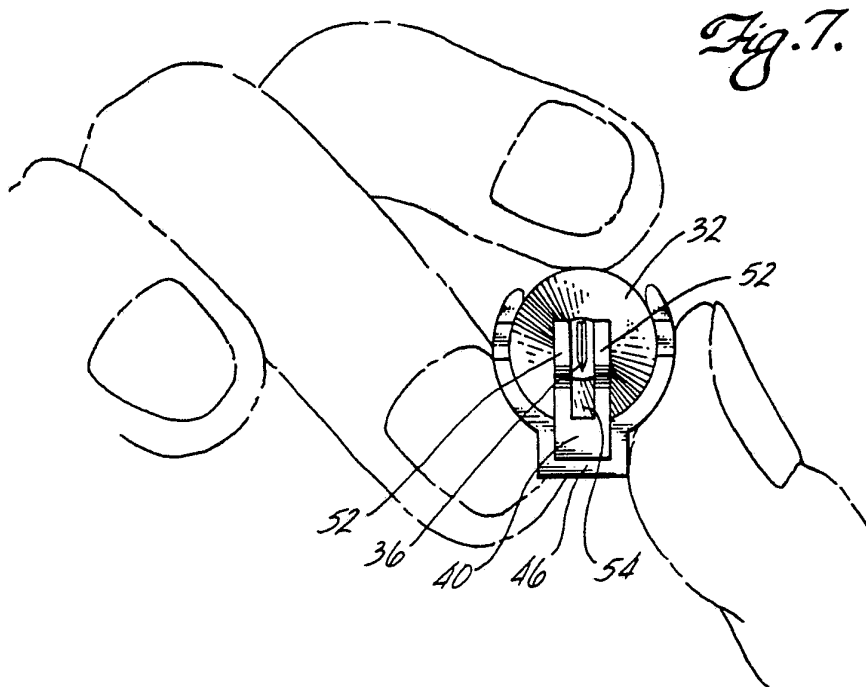
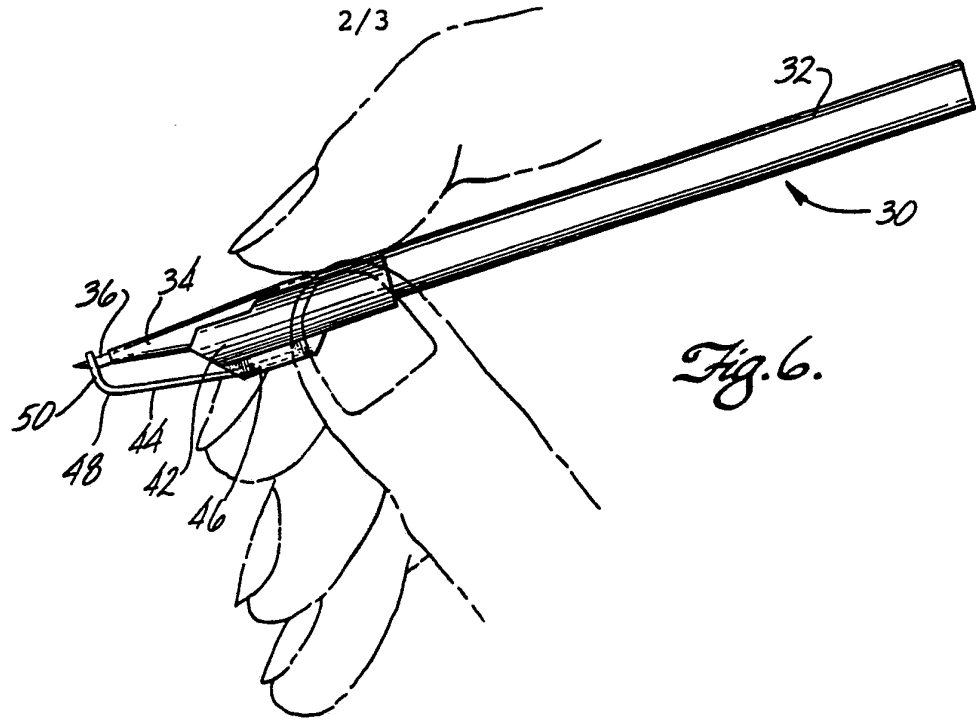
 the number of scalpels (30) in each set
being preselected in accordance with the statistical
20 probability that a cut of the depth characterized by
the set will be required in the performance of that
number of procedures which is substantially equal to
the number of scalpels in the kit.

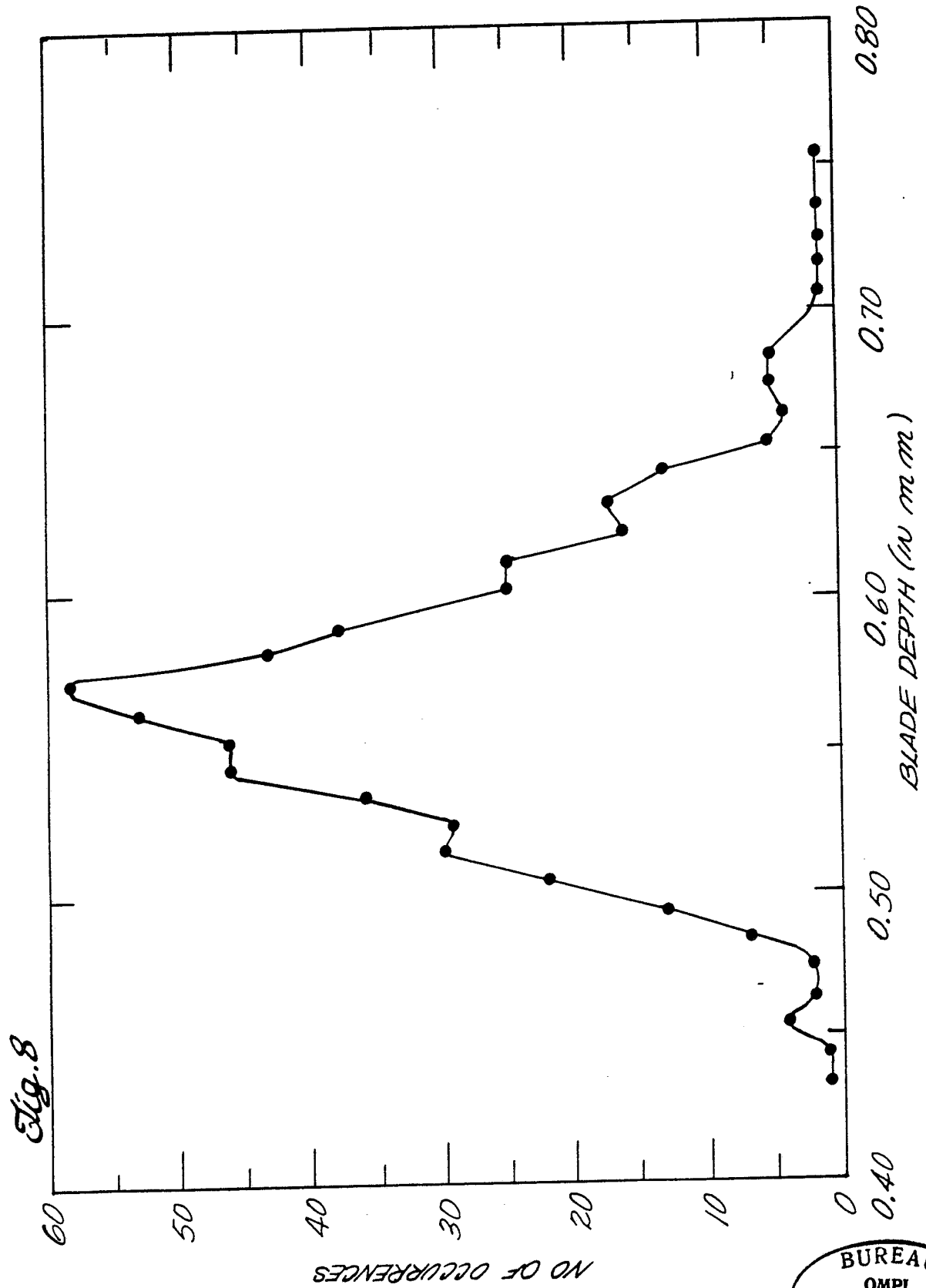
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INTERNATIONAL SEARCH REPORT

International Application No **PCT/US83/01575**

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 U.S. CL: 128/305; 30/294 IPC: A61B 17/32		
II. FIELDS SEARCHED Minimum Documentation Searched ⁴ Classification Symbols U.S. 128/305,314; 30/286-287,293-294,320,353		
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 *	Citation of Document, ¹⁵ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
Y,E Y Y,X Y A Y Y A Y A A A	US, A, 4,408,396 (SCHOLL) 11 October 1983 US, A, 4,373,263 (AYERS) 15 February 1983 US, A, 4,324,044 (SHAHINIAN, Jr.) 13 April 1982 US, A, 4,180,075 (MARINOFF) 25 December 1979 US, A, 3,945,117 (BEAVER) 23 March 1976 US, A, 3,898,735 (HIMENO) 12 August 1975 US, A, 3,892,038 (NOVAK) 1 July 1975 US, A, 3,670,733 (CARLISLE) 20 June 1972 US, A, 2,743,523 (HONEY) 1 May 1956 GB, A, 194,892 (MERRY) 22 March 1923 US, A, 1,195,169 (ADCOCK) 22 August 1916 US, A, 137,404 (BAUER) 1 April 1873	(1,4) (1,2,4) (1-7) (1,7) (1,2,4,6,7) (1,2,4,6,7) (6)
* Special categories of cited documents: ¹⁵ "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "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) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "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 "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "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. "A" document member of the same patent family		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search ¹ 14 December 1983		Date of Mailing of this International Search Report ² 30 DEC 1983
International Searching Authority ¹ ISA/US		Signature of Authorized Officer ¹⁰ C. FRED ROSENBAUM