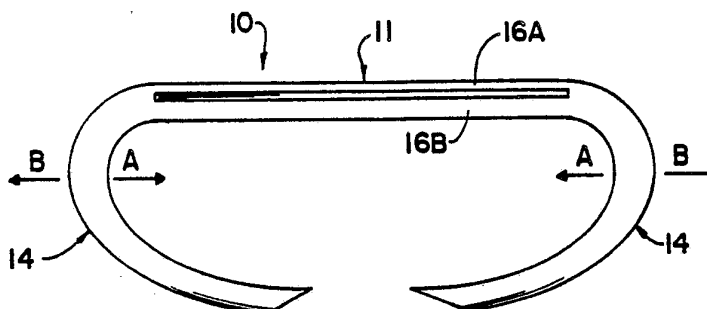




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US88/03873</p> <p>(22) International Filing Date: 31 October 1988 (31.10.88)</p> <p>(31) Priority Application Number: 118,746</p> <p>(32) Priority Date: 6 November 1987 (06.11.87)</p> <p>(33) Priority Country: US</p> <p>(71) Applicant: OPHTHALMIC VENTURES LIMITED PARTNERSHIP [US/US]; 685 Canton Street, Norwood, MA 02062 (US).</p> <p>(72) Inventor: RICHARDS, William, D. ; 167 Holliston Street, Medway, MA 02053 (US).</p> <p>(74) Agent: PANDISCIO, Mark, J.; Schiller, Pandiscio & Kusmer, 125 CambridgePark Drive, Cambridge, MA 02140 (US).</p>	<p>(81) Designated States: AT (European patent), BE (European patent), CH, CH (European patent), DE, DE (European patent), FR (European patent), GB, GB (European patent), IT (European patent), JP, LU (European patent), NL, NL (European patent), SE (European patent).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>	

(54) Title: ADJUSTABLE SURGICAL STAPLE AND METHOD OF USING



(57) Abstract

An adjustable surgical staple (10) for use in joining together two pieces of human or animal tissue. The staple has a spine (11) and two legs (14), with the spine being slotted along its length so as to divide the spine into two separate cross members (16A) and (16B). Bending the cross members towards or away from one another alters the distance between the leg portions of the staple, thereby allowing precise adjustment of the tension of the joiner between the tissues being joined.

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"ADJUSTABLE SURGICAL STAPLE AND METHOD OF USING"

And

Method Of Using The Same

Field Of The Invention

This invention relates to surgical fastening devices in general, and more particularly to surgical staples of the sort used to fasten together human or animal tissue.

Background Of The Invention

Various surgical stapling devices and staples have been devised for closing wounds or incisions during surgical operations. One of the main reasons for their acceptance as a substitute for conventional suturing is that suturing tends to be very time consuming. A surgeon can frequently close a wound using a surgical stapling device and staples in a minute or two that would otherwise require ten or fifteen minutes to suture. This saving of time is of substantial importance, since it (a) reduces the length of time the patient must be maintained under anesthesia, (b) reduces the surgeon's time, (c) reduces the surgeon's fatigue, and (d) frees up the operating room faster so that it can be used for other surgical procedures.

A number of recent advances in surgical stapling devices and staples have been directed to increasing the variety of surgical procedures in which they can be effectively used. See, for example, the surgical stapling devices and staples described and illustrated

in pending U.S. Patent Application Serial No. 906,151, filed 9/11/86 by William D. Richards et al. for "Surgical Microstapler" (Attorney's Docket No. OVLP-4), pending U.S. Patent Application Serial No. 906,150, filed 9/11/86 by William D. Richards et al. for "Driver for Surgical Microstapler" (Attorney's Docket No. OVLP-5), pending U.S. Patent Application Serial No. 944,951, filed 12/22/86 by William D. Richards et al. for "Ophthalmic Stapler" (Attorney's Docket No. OVLP-3), and the pending U.S. patent application filed 11/3/87 by William D. Richards et al. for "Surgical Stapling System" (Attorney's Docket No. OVLP-6). Such surgical stapling devices and staples may be made of such dimensions, and are designed to so minimize stapling trauma to the tissues being joined, that they may be used for delicate surgeries, e.g. ophthalmic surgery or plastic surgery.

However, in some surgeries the need to precisely control the tension of the joinder between the tissues makes even these surgical stapling devices and staples less advantageous than conventional suturing. Such control over the tension of the joinder between the tissues can be particularly important in some types of ophthalmic surgery, e.g. such as where the curvature of the eye must be precisely regulated to minimize optical problems, and some types of plastic surgery, e.g. such as where relative positioning of the tissues must be precisely regulated to minimize cosmetic problems.

Objects Of The Invention

Accordingly, the primary object of the present invention is to provide an adjustable surgical staple which allows the surgeon to adjust the tension of the joinder between the tissues being joined after the staple has been deployed in the tissue.

Another object of the present invention is to provide an adjustable surgical staple which includes novel holding means for enhancing the holding power of the staple in the tissue, whereby the surgeon may manipulate the staple after deployment so as to adjust the tension of the joinder between the tissues being joined without dislodging the staple from the tissue.

Yet another object of the present invention is to provide a novel method for joining together two pieces of tissue using an adjustable surgical staple which allows the surgeon to adjust the tension of the joinder between the tissues being joined after the staple has been deployed in the tissue.

Summary Of The Invention

These and other objects of the present invention are achieved through the use of a novel surgical staple which comprises a spine having first and second opposite ends, and first and second legs, the first leg being attached to the first end of the spine and the second leg being attached to the second end of the spine, wherein the spine is slotted along its length so as to comprise two separate cross members. It is also preferred that each of the staple's legs include a plurality of tiny barbs thereon to enhance the holding

power of the staple in the tissue.

During use, the staple is deployed across an incision so that one leg of the staple is disposed on either side of the incision and the spine extends across the incision. The tension of the joinder between the tissues being joined may then be precisely adjusted by manipulating the two cross members toward or away from one another, whereby the spacing between the staple's two legs may be precisely regulated.

Brief Description Of The Drawings

These and other objects and features of the present invention will be more fully described or rendered obvious in the following detailed description of the invention, which is to be considered together with the accompanying drawings wherein like numbers refer to like parts and further wherein:

Fig. 1 is a perspective view of an adjustable surgical staple which comprises a first embodiment of the present invention, showing the staple prior to its deployment into tissue;

Fig. 2 is an enlarged perspective view of a portion of one leg of the same surgical staple, showing the plurality of tiny barbs formed on each leg of the staple;

Fig. 3 is a top plan view of the same surgical staple taken during an intermediate step of fabrication (prior to having its two legs bent upward and then downward in the manner shown in Fig. 1), showing the sizing of the staple's tiny barbs relative to the staple as a whole;

Fig. 4 is a perspective view of the same surgical staple, showing the staple after its deployment into tissue;

Fig. 5 is a perspective view of an adjustable surgical staple which comprises a second embodiment of the present invention, showing the staple prior to its deployment into tissue;

Fig. 6 is a perspective view showing the staple of Fig. 5 after its deployment into tissue;

Fig. 7 is a perspective view of an adjustable surgical staple which comprises a third embodiment of the present invention, showing the staple prior to its deployment into tissue; and

Fig. 8 is a perspective view showing the staple of Fig. 7 after its deployment into tissue.

Detailed Description Of The Invention

Looking first at Fig. 1, there is shown a surgical staple 10 which comprises a first embodiment of the present invention. Surgical staple 10 comprises a spine 11 and a pair of identical legs 14. Spine 11 is bisected along its length by a slot 15. Slot 15 divides the spine into two identical, parallel cross members 16A and 16B. Legs 14 are curved so as to extend first upward and then downward from spine 11, and legs 14 terminate in sharp points 17. Preferably slot 15 extends upward along the upwardly-extending portions of legs 14 and terminates prior to reaching the highest points (or "knees") of the legs, as shown in Fig. 1.

Looking next at Fig. 2, a plurality of tiny barbs 18 are preferably (but not necessarily) formed along

each of the legs 14 near sharp points 17. Barbs 18 are sufficiently large that they significantly enhance the holding power of the staple when the staple has been deployed in tissue, as will hereinafter be described in further detail, yet are sufficiently small that they will cause minimal trauma to the tissue if and when the staple is subsequently removed.

Fig. 3 illustrates the sizing of the staple's tiny barbs 18 relative to the staple as a whole; in this connection, it is to be appreciated that Fig. 3 shows the surgical staple during an intermediate stage of fabrication, wherein the staple at this point is a flat strip and its two legs have not yet been bent upward and then downward in the manner shown in Fig. 1.

Staple 10 (Fig. 1) is generally similar in form to a staple of the type disclosed in the aforementioned U.S. Patent Application Serial No. 906,151, the specification and drawings of which are hereby incorporated herein by reference, and is intended to be deployed into tissue in the same general manner as a staple of the type disclosed in the above-identified U.S. Patent Application Serial No. 906,151. More specifically, a plurality of staples 10 are created together in the form of a unitary staple strip or magazine of the type disclosed in the above-identified U.S. Patent Application Serial No. 906,151, and the staples are intended to be deployed into tissue using a surgical stapler of the type disclosed in U.S. Patent Application Serial No. 906,151. It is to be appreciated that once a staple 10 has been deployed in tissue in the foregoing manner, it will have assumed

the shape shown in Fig. 4, wherein the staple's spine 11 will extend across an incision in the tissue and the two legs 14 are anchored in the tissue on opposite sides of the incision. In the course of deployment, the staple's legs 14 will have been bent downward and inward so that sharp points 17 are oriented towards one another, as shown in Fig. 4. It will be appreciated that those portions of legs 14 which include slot 15 will have been bent so as to extend generally parallel to spine 11, thereby effectively forming flat extensions to the spine, in the manner shown in Fig. 4.

Once staple 10 has been deployed in tissue in the foregoing conventional manner, the surgeon may thereafter utilize the unique characteristics of staple 10 to precisely adjust the tension of the joinder between the tissues being joined. The surgeon does this by manipulating cross members 16A and 16B toward or away from one another, which results in a corresponding adjustment of the spacing between legs 14, and hence a corresponding adjustment of the tension of the joinder between the tissues being joined. More specifically, if the surgeon wishes to tighten the joinder between the tissues, he forces cross members 16A and 16B apart, whereby legs 14 will be moved inward in the direction of the arrows A (see Fig. 4), so that the distance between the legs will decrease and the two pieces of tissue being joined by the staple will be brought closer together. Correspondingly, if the surgeon thereafter wishes to loosen the joinder between the tissues, he forces cross members 16A and 16B together, whereby legs 14 will be eased outward in the

direction of the arrows B (see Fig. 4) so that the distance between the legs will increase and the two pieces of tissue being joined by the staple will be eased further apart. Of course, it will be appreciated that the staple shown in Figs. 1 and 4 can never have its legs further apart than they are when the staple is first set, since at the time of setting the cross members 16A and 16B will extend perfectly parallel to one another and manipulation of the cross members either towards or away from one another can only shorten the distance between the legs. However, it will also be appreciated that once legs 14 have been brought closer together by manipulation of the cross members, they can then be spread apart again by further manipulation of the cross members in the manner previously described.

From the foregoing it will be appreciated that staple 10 must be formed out of a material which is simultaneously strong, bendable, and capable of holding a bent configuration until subjected to a further force adequate to cause it to further bend or unbend, inasmuch as staple 10 must be capable of both holding together tissue and being adjustable through manipulation of its cross members 16A and 16B. Staple 10 must also be formed out of a material which is biocompatible with the tissue it is deployed in. It has been found, or it is believed, that satisfactory staples may be formed out of conventional materials such as 316L stainless steel. Still other materials will be well known to those skilled in the art.

It is also to be appreciated that certain

modifications may be made to the preferred embodiment described above without departing from the scope of the present invention.

Thus, for example, the tiny barbs 18 could be omitted from the staple legs and a more conventional staple leg design utilized. However, it is to be appreciated that tiny barbs 18 serve an important function inasmuch as they enhance the holding power of the staple in the tissue, whereby the staple will remain solidly anchored in the tissue even as cross members 16A and 16B are adjusted relative to one another. It is also to be appreciated that tiny barbs 18 simultaneously allow a deployed staple to be deliberately removed at some future date without causing excessive trauma to the joined tissue. The size, shape, and location of the barbs may also be varied.

The present invention could also be practiced with staples that are similar to the one shown in Fig. 1, except that slot 15 is shortened so as to terminate within spine 11 instead of extending upward along the upwardly-extending portions of legs 14.

It is also anticipated that the present invention may be practiced with staples having a shape other than that shown in Fig. 1, e.g. it could be used with a staple having a shape as shown in Figs. 5 and 6, wherein the staple's cross members are bowed away from one another. This construction has the advantage that the initial spacing between the legs when the staple is deployed can be increased, since the cross members are not yet parallel at the time of deployment. With the

staple of Figs. 5 and 6, legs 14 could be eased outwardly from one another immediately after deployment simply by forcing cross members 16A and 16B towards one another, i.e., by removing the outward bow in each cross member.

Alternately, the present invention may be practiced with a conventional, U-shaped staple such as that shown in Fig. 7, wherein the legs 14 are straight and extend at a substantially right angle from the spine. The staple is set in place using an anvil-equipped stapler. Fig. 8 shows the shape of the staple of Fig. 7 after it has been set in place. In this situation, the length of slot 15 in the spine may be relatively short or long, as desired, and the legs of the staple may or may not include tiny barbs as shown in Figs. 2 and 3.

Still other changes of this type will be obvious to persons skilled in the art and are considered to be within the scope of the present invention.

Advantages Of The Invention

Numerous advantages are achieved by utilizing the present invention.

First, the present invention provides an adjustable surgical staple which allows the surgeon to precisely adjust the tension of the joinder between the tissues being joined after the staple has been deployed in the tissue.

Second, the present invention provides an adjustable surgical staple which includes novel holding means for enhancing the holding power of the staple in the tissue, whereby the surgeon may manipulate the

staple after deployment so to precisely adjust the tension of the joiner between the tissues being joined without dislodging the staple from the tissue.

Third, the present invention provides a novel method for joining together two pieces of tissue using an adjustable surgical staple which allows the surgeon to precisely adjust the tension of the joiner between the tissues being joined after the staple has been deployed in the tissue.

Fourth, the present invention provides a staple whose spine, because it is bisected by a slot, has greater flexibility, smaller size, and nearly the same strength as a conventional staple spine; as a result, the staple may provide less lid irritation when used in ophthalmic surgery, and may allow further manipulation of the staple by the surgeon after deployment without causing the staple to loosen in the tissue.

Fifth, the present invention provides an adjustable surgical staple that may be made in various sizes, depending on its application. By way of example, for ophthalmic purposes, the staple of Fig. 1 might have a length, in its unbent state (i.e., that of Fig. 3), of 0.109 inches.

What Is Claimed Is:

1. An adjustable surgical staple comprising:
a spine having first and second opposite ends, and
first and second legs, said first leg being
attached to said first end of said spine, and said
second leg being attached to said second end of said
spine,
said spine being slotted along its length so as to
comprise two separate cross members, whereby
manipulation of said cross members toward and away from
one another will result in changes in the spacing
between said first and second legs.
2. An adjustable surgical staple according to
claim 1 wherein each of said legs includes a plurality
of tiny barbs thereon.
3. An adjustable surgical staple according to
claim 1 wherein a portion of each of said legs is also
slotted, said legs being slotted adjacent said spine.
4. An adjustable surgical staple according to
claim 1 wherein said cross member initially extend
parallel to one another.
5. An adjustable surgical staple according to
claim 1 wherein said cross members do not initially
extend parallel to one another.

6. In a surgical staple of the type comprising a spine having first and second opposite ends, and first and second legs, said first leg being attached to said first end of said spine, and said second leg being attached to said second end of said spine,

the improvement wherein:

said spine is slotted along its length so as to comprise two separate cross members that may be manipulated toward or away from one another so as to change the spacing between said first and second legs.

7. A surgical staple according to claim 6 wherein each of said legs includes a plurality of tiny barbs thereon.

8. An adjustable surgical staple according to claim 6 wherein a portion of each of said legs is also slotted, said legs being slotted adjacent said spine.

9. An adjustable surgical staple according to claim 6 wherein said cross members initially extend parallel to one another.

10. An adjustable surgical staple according to claim 6 wherein said cross members do not initially extend parallel to one another.

11. A method for attaching together two pieces of tissue, said method comprising the steps of:

(1) providing an adjustable surgical staple, said adjustable surgical staple comprising:

a spine having first and second opposite ends, and first and second legs, said first leg being attached to said first end of said spine, and said second leg being attached to said second end of said spine,

said spine being slotted along its length so as to comprise two separate cross members that may be manipulated toward or away from one another so as to change the spacing between said first and second legs,

(2) deploying said adjustable surgical staple in the two pieces of tissue to be joined so that said first leg is disposed in one piece of tissue and said second leg is disposed in said second piece of tissue; and

(3) manipulating said cross members towards and away from one another so as to precisely adjust the tension of the joinder between said two tissues being joined.

12. A method according to claim 11 wherein each of said legs includes a plurality of tiny barbs thereon.

13. A method according to claim 11 wherein a portion of each of said legs is also slotted, said legs being slotted adjacent said spine.

14. A method according to claim 11 wherein said cross members initially extend parallel to one another.

15. A method according to claim 11 wherein said cross members do not initially extend parallel to one another.

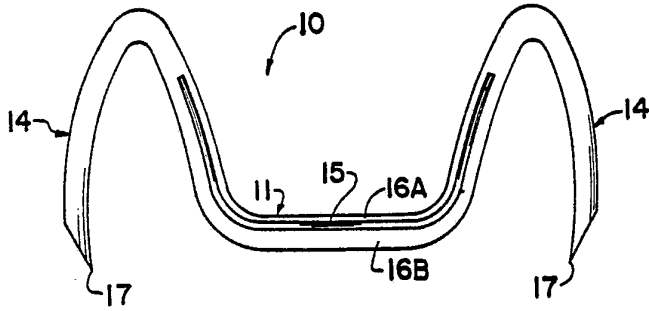


Fig. 1

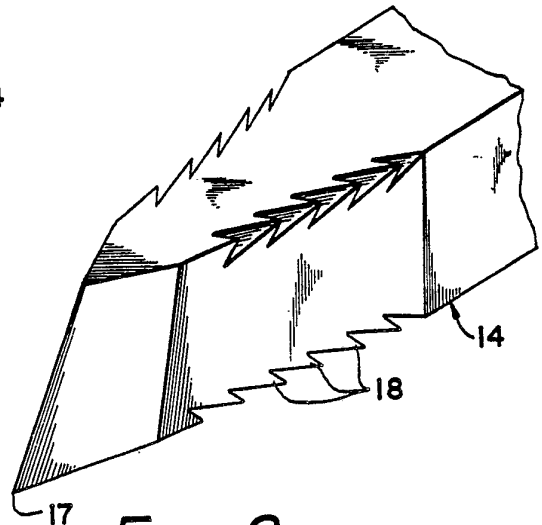


Fig. 2

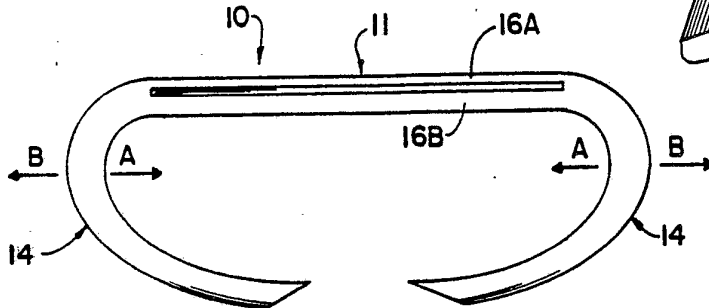


Fig. 4

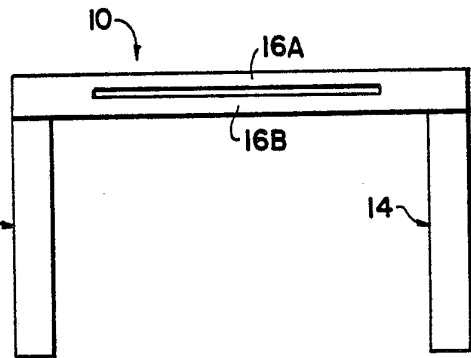


Fig. 7

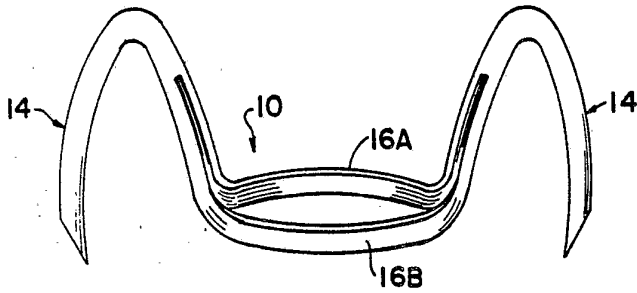


Fig. 5

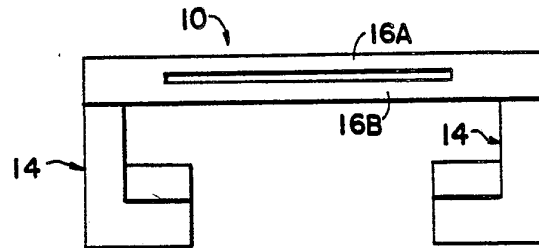


Fig. 8

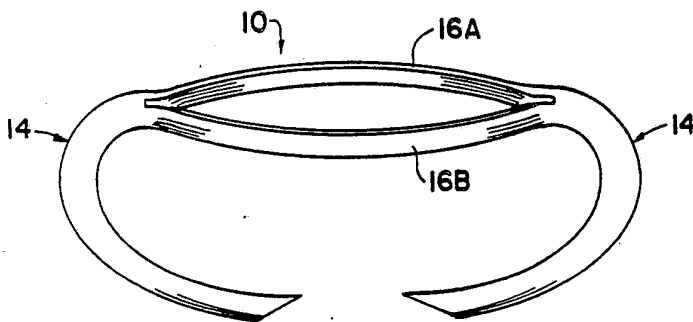


Fig. 6

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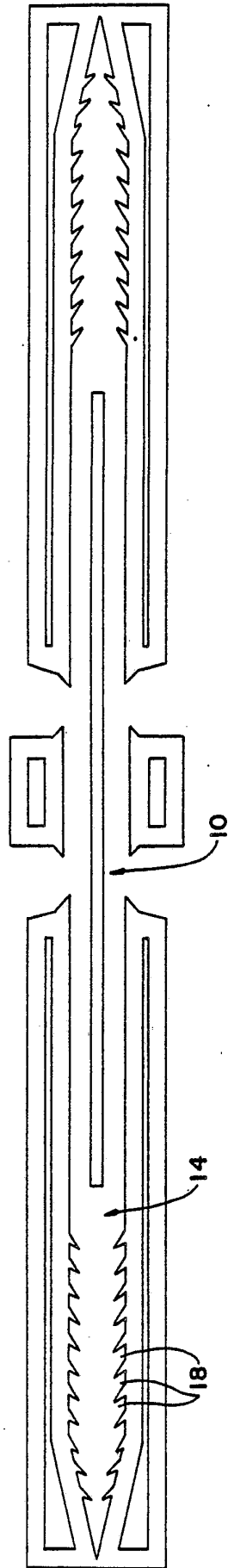


Fig. 3

INTERNATIONAL SEARCH REPORT

International Application No. **PCT/US88/3873**

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC (4): A61B 17/08, 17/04 U.S. Cl: 128/337, 335, 334R		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
U.S.	128/335, 337, 334R 411/457, 458, 473, 484, 471	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	US,A, 1,983,373 (HORTON) 04 December 1934 see column 2, lines 102-110; column 3, lines 1-20.	1,3,4,8,9
X	US,A, 1,412,582 (VAILE) 11 April 1922 see column 1, lines 29-34.	1,4,6,9
X	US,A, 192,121 (JOHNSON) 19 June 1877 see column 1, lines 29-34.	1,4,6,9
<u>X</u> Y	US,A, 2,111,404 (PANKONIN) 15 March 1938 see column 5, lines 1-20.	2,7
<u>X</u> Y	US,A, 4,570,623 (Ellison) 18 February 1986 see column 2, lines 13-17.	2,7
<u>X</u> Y	US,A, 4,458,387 (PEARSON) 10 July 1984 see column 3, lines 32-65.	2,7
Y	US,A, 4,321,002 (FROEHLICH) 23 March 1982 see Figures 8 and 9	5,10
<p>* Special categories of cited documents: ¹⁰</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	Date of Mailing of this International Search Report	
11 January 1989	9 - MAR 1989	
International Searching Authority	Signature of Authorized Officer	
ISA/US	<i>Gary Jackson</i> Gary Jackson	

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A	US,A, 3,107,390 (SHELTON) 22 October 1963 see Figure 5	1-10
A	US,A, 1,477,230 (PANIAN) 11 December 1923 see Figures 4 and 5.	1-10

V. OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. Claim numbers because they relate to subject matter ¹² not required to be searched by this Authority, namely:

2. Claim numbers because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out ¹³, specifically:

3. Claim numbers, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ²

This International Searching Authority found multiple inventions in this international application as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- The additional search fees were accompanied by applicant's protest.
- No protest accompanied the payment of additional search fees.