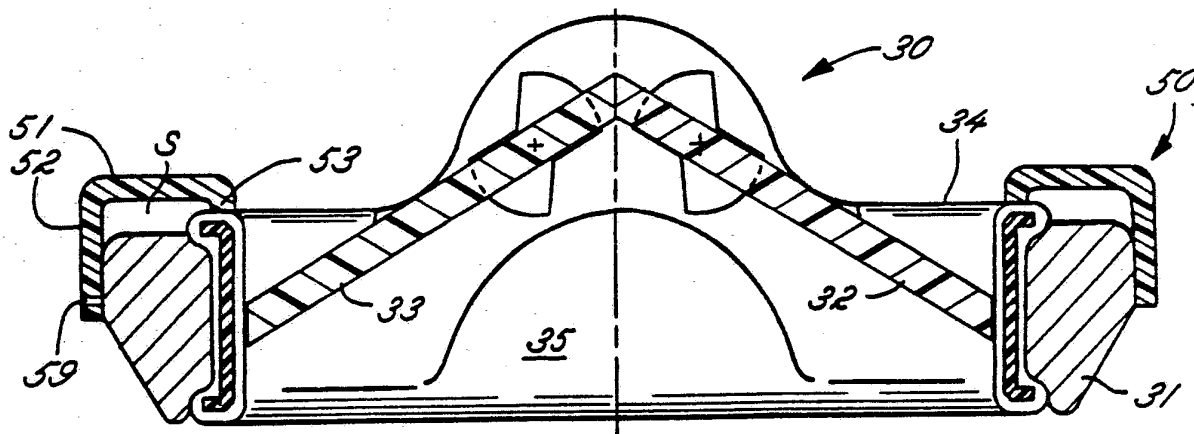




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(54) Title: PROTECTIVE SHIELD FOR PROSTHETIC HEART VALVES

**(57) Abstract**

The invention relates to a protective shield (40) which covers the sewing cuff (21) and sutures of implanted prosthetic heart valves. The protective shield is made from, or coated with, a material that is bio and blood-compatible and non-thrombogenic, such as polished pyrolytic carbon or acetal polymer. The protective shield typically consists of a ring (51) with optimal inner (53) and outer flanges (52) to accommodate various prosthetic heart valve designs.

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PROTECTIVE SHIELD FOR PROSTHETIC HEART VALVES

BACKGROUND OF THE INVENTION

The present invention relates to prosthetic heart valves and more particularly to a protective shield for the use in prosthetic heart valves to completely and precisely cover the sewing cuff, sutures, knots, and cut ends of sutures associated with the heart valve.

Heart valve prostheses are known to the prior art in two basic forms: mechanical and biological/tissue or bioprotheses. Essentially, such prostheses are formed of a base member adapted to be secured to the patient's tissue and having a blood passage way, and a valving member for controlling the flow of blood through the passage way. Typical valving members found in prior art mechanical heart valve prostheses include an occluder in the form of a ball, leaflet, or disc which moves between open and closed positions to control blood flow. The occluder is typically retained in an operative relation to the passage way with an appropriate mechanism, such as a hinge pin, cage, or a projection from the base.

In the tissue valves (bioprotheses) the valving portion may be a valve from another human, from an animal, or a similar valve constructed from appropriate human or animal tissues. Synthetic materials may be substituted for tissue in some designs.

A common feature of all prior art prosthetic heart valves is a suturing or cuff member associated with the device. It is this cuff member which is attached to the recipient's tissue. In attaching the cuff to the recipient's tissue, there are typically sutures and knots, cut ends of sutures, and exposed fabric surfaces, which all can cause, among other postoperative complications, prosthesis thrombosis,

thromboembolism, tissue ingrowth causing malfunctions and, in the case of mechanical valves, disc or leaflet entrapment by suture ends cut abnormally long.

SUMMARY OF THE INVENTION

The present invention diminishes the above postoperative complications present in prior art prosthetic heart valves. Specifically, the present invention provides a protective shield made of non-thrombogenic material to completely and precisely cover the sewing cuff, knots, and cut ends of sutures to reduce thromboembolism formation, confine tissue growth and prevent interference with valve operation.

The protective shield may be designed and sized to fit existing prosthetic heart valves. To this end, the protective shield may have any of a variety of geometric cross sections which would facilitate the objects of the invention as set forth above. Examples of such cross sections are L-shaped, curved, flat, concave or convex. Typically a protective shield according to the invention will be annular or ring-shaped to fit over a circular valve base and cover an annular sewing cuff. In one embodiment discussed in more detail below, the ring-shaped member has a substantially L-shaped cross section with an outer flange to cover a substantial portion of an otherwise-exposed sewing cuff. It will be appreciated from the above discussion and from the discussion which follows that other designs may be adapted to a variety of heart valve designs.

The various configurations of protective shields may be attached to the valves in a variety of ways, including by friction between valve and shield

sutures, by suturing through eyelets attached to the protective shield or by snapping into place.

The versatility of this device renders it useful for many types of prosthetic heart valves including mechanical, biological and synthetic types. It is contemplated that little or no change in design in any of these different prostheses is necessary for the use of the present invention, the configuration of which may be modified as appropriate for valve type, site and size.

From the above it will be appreciated that a primary object of the present invention is to minimize, through the use of an easily-installed shield, the occurrence of the above-mentioned complications with little or no modification to existing valve designs.

It is a more specific object to prevent the formation and circulation of thromboemboli which may form, as part of the healing process, on exposed fabric and sutures of prosthetic heart valves.

It is a further object of the present invention to confine suture ends to prevent their serving as a nidus for thromboembolis or their entrapment within the valve occluder mechanism, which can result in restricted occluder motion and valve malfunction.

Additionally, it is an object of the present invention to prevent ingrowth of the recipient's tissues into the valve mechanism while allowing healing to proceed in a normal fashion underneath the shield.

The foregoing and other objects of the present invention, as well as the invention itself, may be more fully understood with the following description when read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a cut-away view of a human heart having mitral and aortic prosthetic valves with protective shields according to the present invention;

Fig. 2 is a cross-sectional view of an aortic prosthetic valve including a shield according to the present invention;

Fig. 3 is a cross-sectional view of a mitral prosthetic valve with another embodiment of a shield according to the present invention; and

Fig. 4 is a cross-sectional view of a third embodiment of a protective shield according to the present invention;

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A cut-away view of a human heart 10 is shown in Fig. 1. For illustrative purposes, the heart is shown with aortic and mitral prosthetic valves 20 and 30, respectively. Figs. 2 and 3, discussed in detail below, illustrate the implanted aortic and mitral valves, respectively. In Fig. 1 the valves are shown in place with sewing cuffs 21 and 31 attaching the devices to heart tissue. Protective shields 40 and 50 according to the present invention are also shown protecting the respective heart sections from exposed sutures, suture knots, cut ends of sutures and tissue ingrowth, all of which can cause the previously-discussed postoperative complications such as prosthesis thrombosis, thromboembolism and/or valve malfunctions.

Referring to Fig. 2, a protective shield 40 is shown in connection with a prosthetic aortic heart valve 20 having an associated suturing member or cuff

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21. While the shield may be used with any of a variety of prosthetic aortic valves, the particular valve depicted is a dual-leaflet mechanical heart valve of the type disclosed in U.S. Patent 4,276,658 and assigned to the present assignee. With such a valve, as explained in detail in the patent, the leaflets 22 and 23 are pivotally mounted to an annular base 24 such that they move in response to the flow of blood to open and close the blood passageway 25.

The protective shield may be made from a material which resists and discourages tissue growth and is bio-compatible, blood-compatible and non-thrombogenic. Examples of such materials considered to be suitable are pyrolytic carbon, titanium, cobalt alloys (such as Vitalium, Stellite and Elgiloy), stainless steel, acetal polymers, PTFE (Teflon), polypropylene polymers, polyurethane polymers, silicone polymers and polysulfone polymers. Materials which have been found to be particularly suitable are polished pyrolytic carbon, graphite coated with pyrolytic carbon, and acetal polymer, of which Delrin is one commercial example. As a point of information, one commercial heart valve of the type disclosed in the referenced patent is fabricated of pyrolytic carbon.

Alternatively, the protective shield may be made of material which invites and encourages a smooth tissue covering or ingrowth and which is bio-compatible, blood-compatible and non-thrombogenic. Examples of suitable materials of this type are: tissue or tissue-derived materials; synthetics such as woven dacron, PTFE etc.; and microporous, roughened, and/or etched materials, such as PTFE, polyurethanes, ceramics, carbons or metals.

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Referring again to Fig. 2, the sewing cuff 21, normally made of biocompatible fabric, is typically sutured directly to the heart tissue (not shown). Such suturing results in knots and loose, cut ends which, as noted above, can cause complications. According to an important aspect of the present invention, the protective shield of the present invention may be designed to cover the fabric sewing cuff and the associated sutures.

Describing the protective shield 40 of Fig. 2 in more detail, it is shown as an annularly-shaped ring having a substantially flat disc member 41 and a cylindrical outer flange 42. Together the disc member 41 and the outer flange 42 serve to cover the sewing cuff, associated sutures, suture knots and cut ends of sutures present in implanting a prosthetic heart valve.

It will be appreciated that in this and the subsequent embodiments the central opening of the protective shield is of sufficient diameter to accommodate the flow of blood through the valve without any interference. The central opening in the shield obviously should also provide clearance for any valve structures, such as stent posts, which project beyond the main body of the valve.

It is contemplated that the shield will typically be installed onto the valve after suturing of the valve to the recipient's heart tissue. Attachment of the shield to the valve may be accomplished in a variety of ways. As illustrated in Fig. 2, holes may be provided in the shield, shown as holes 49 in flange 42, to permit the shield to be sutured onto the valve 20 and/or sewing cuff 21. Eyelets fabricated on the protective shield surface proximal to the sewing cuff may be also used for the

attachment with sutures. Alternatively, or in addition, the shield may be retained in place using a frictional, adhesive or snap fit between surfaces of the shield and the valve and/or sewing cuff. As further alternatives, attachment may be via hooks or Velcro®-type fasteners.

Another embodiment of the heart valve shield of the present invention is shown as item 50 in Fig. 3 in conjunction with a mitral prosthetic valve 30. The valve shown is again of the type disclosed in U.S. Patent 4,276,658. This embodiment differs from that shown in Fig. 2 in that shield 50 has an inner flange 53 in addition to the outer flange 52. The inner flange may serve to space the ring 51 off the valve base 34 and the sewing cuff 31 to provide more space (depicted as S) to accommodate knots, cut suture ends, etc. Such an inner flange may also serve to accommodate other types of prosthetic valves and/or sewing cuffs. As with the embodiment of Fig. 2, the shield 50 can be secured to the valve 30 through suturing holes 59, via a frictional or snap fit, or via a variety of other suitable techniques.

Another embodiment is shown in Fig. 4 wherein the protective shield is a substantially conical disc 60 with no inner or outer flanges. Attachment is via a frictional fit between the inner diameter 61 of the disc and the outer diameter 71 of the valve 70. It should be again appreciated that, depending upon designs of particular heart prostheses, the thickness, inside and outside diameters and the conical angle θ may be adapted to accommodate the particular heart valve and associated cuff member.

Several actual embodiments of the protective shield according to the invention have been fabricated and are described in the following Examples.

Example 1

A protective shield of the type depicted in Fig. 4 was constructed of pyrolytic carbon coated onto a graphite substrate to fit over the cuff of a 23 mm dual leaflet heart valve of the type disclosed in U.S. Patent No. 4,276,658. The shield was sized for attachment to the valve by a friction fit. The thickness of the coated ring was 0.018 inches, though it is contemplated that the thickness may be in the range of 0.0005 inches to 0.050 inches, preferably within the range of 0.015 to 0.020 inches. The central aperture of the ring had a diameter in the range of 0.840 to 0.860 inches to accommodate the flow of the specific size valve and to achieve a friction fit. The ring of the shield was angled 30° from the horizontal for this example.

Example 2

The protective shield of this example was of the type depicted in Fig. 3. A graphite substrate consisting of a planar ring about 0.016 inches thick, with descending flanges on the inside and outside diameters, was machined. The inside diameter of the ring of the substrate was approximately 0.852 inches; the outside diameter about 1.140 inches. The outer flange height to the top surface of the annular disc was 0.140 inches, and the internal flange height was about 0.040 inches. Three 0.050 inch diameter holes were drilled in the outer flange, each hole center being 120° from the others, with the hole centers being 0.05 inches above the bottom edge of the flange. This substrate was coated with pyrolytic carbon, yielding a ring of 0.790 inches inside diameter, 1.210 inches outside diameter and having an

outer flange height of 0.210 inches before secondary machining and polishing. Therefore, the coating thickness "as coated" was about 0.025 to 0.035 inches. Because substrate holes were overcoated, however, that coating was considered to be excessive. It is planned to make additional rings of this form with a coating thickness "as coated" of about 0.005 to 0.015 inches.

Example 3

An acetal polymer (Delrin) shield of the type depicted in Fig. 2 was machined for a 27mm dual-leaflet valve of the type disclosed in U.S. Patent 4,276,658. The shield was 0.025 to 0.030 inches thick. In this embodiment, the shield consisted of a planar ring having an inside diameter of about 0.985 inches and an outside diameter of about 1.345 inches. An outer flange descended vertically about 0.125 inches from the top surface of the horizontal planar ring. Three pairs of 0.040 inch holes were drilled, each pair at 120° from the others in the descending flange, with the hole centers being about 0.03 inches above the bottom of the flange. Adequate retention of the shield to the 27mm valve was demonstrated using sutures which passed through both holes of each pair and also by sutures which passed through only one hole of each pair.

Example 4

A shield similar to that described in Example 3, only of the Fig. 3 (dual-flange) type, was machined from Delrin. The intent of this model was to provide increased covering of the sewing cuff and to create a space above the cuff for suture ends and knots. To accomplish the first aim, the height of the outside

diameter descending flange was increased to 0.230 inches. To accomplish the second aim, an inside diameter descending flange 0.050 inches high was added. For this example, the pairs of holes were replaced by individual holes, each 120° from the others.

By contrasting the embodiments shown in Figs. 2-4 and those described in the Examples it will be appreciated that the configuration of the shield may vary in order to accommodate various prosthetic valve and sewing cuff designs. With all embodiments, however, it is to be understood that the purpose of the protective shield is to reduce complications by confining the sewn tissue and covering at least a portion of the sewing cuff, the sutures, suture knots and cut ends of sutures associated with attaching a prosthetic heart valve to a recipient's tissue. Accordingly, it will be appreciated that the invention is not limited to the embodiments described above. Instead the invention extends to variations not constituting departures from the spirit and scope of the invention.

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I Claim:

1. A protective shield for a heart valve prosthesis comprising an annular ring member fabricated from a bio-compatible, blood-compatible, and non-thrombogenic material and adapted to fit over at least the portion of the prosthesis which attaches directly to the recipient's heart tissue to confine sutures, suture knots and cut ends of sutures.
2. A protective shield as claimed in claim 1 comprising essentially an L-shaped cross section with an outer flange extending downwardly from the plane of an annular disc member.
3. A protective shield as claimed in claim 1 comprising a substantially channel-shaped cross section with both outer and inner flanges extending downwardly from the plane of an annular disc member.
4. A protective shield as claimed in claim 1 wherein the surface of said annular ring member in the plane thereof is substantially conical.
5. A protective shield as claimed in claim 1 wherein said shield is fabricated from a material which resists and discourages tissue growth.
6. A protective shield as claimed in claim 5 wherein said shield is fabricated from polished pyrolytic carbon.

7. A protective shield as claimed in claim 1 wherein said shield is fabricated from graphite coated with pyrolytic carbon.

8. A protective shield as claimed in claim 1 wherein said shield is fabricated from acetal polymer.

9. A protective shield as claimed in claim 1 wherein said shield is fabricated from a material which invites and encourages a smooth tissue covering or ingrowth.

10. A protective shield as claimed in claim 9 wherein said shield is fabricated from tissue or tissue-derived materials.

11. A protective shield as claimed in claim 9 wherein said shield is fabricated from a microporous roughened and/or etched material.

12. A protective shield as claimed in claim 11 wherein said shield is fabricated from a material selected from the group consisting of PTFE, polyurethane, ceramic, carbon and metal.

13. A protective shield as claimed in claim 1 wherein said shield further comprises attaching means for attaching said shield to said heart valve prosthesis.

14. A protective shield as claimed in claim 13 wherein said attaching means comprises eyelets attached to said shield to allow for suturing therethrough.

15. A protective shield as claimed in claim 1 wherein at least one of the surfaces of said shield is sized relative to the mating surface of a heart valve prosthesis to provide a frictional fit between said one of said shield surfaces and said mating surface of said heart valve prosthesis.

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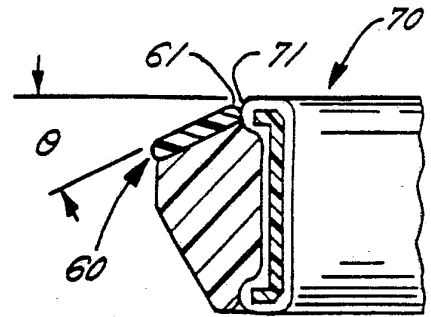
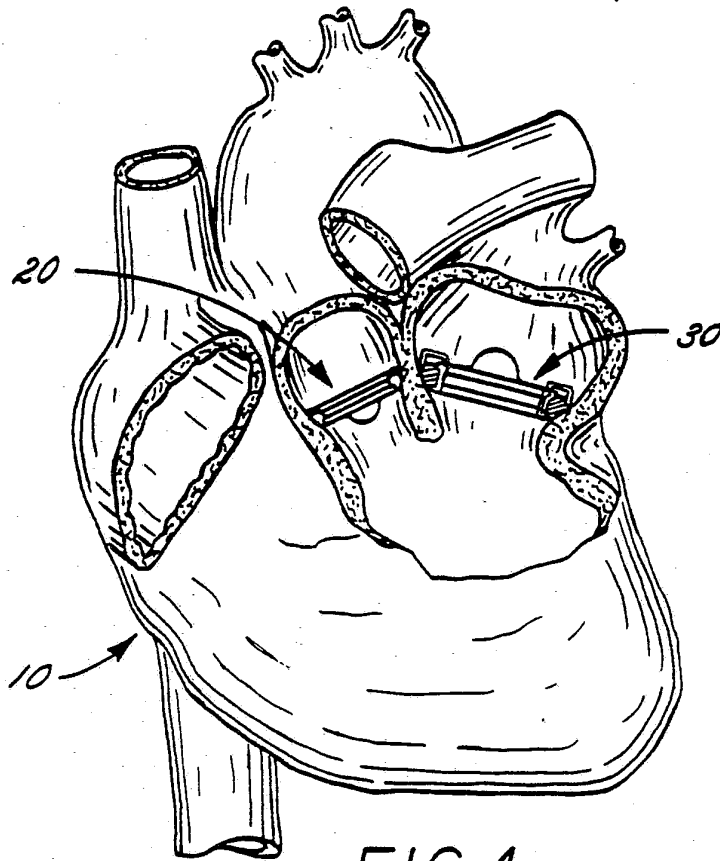


FIG. 4

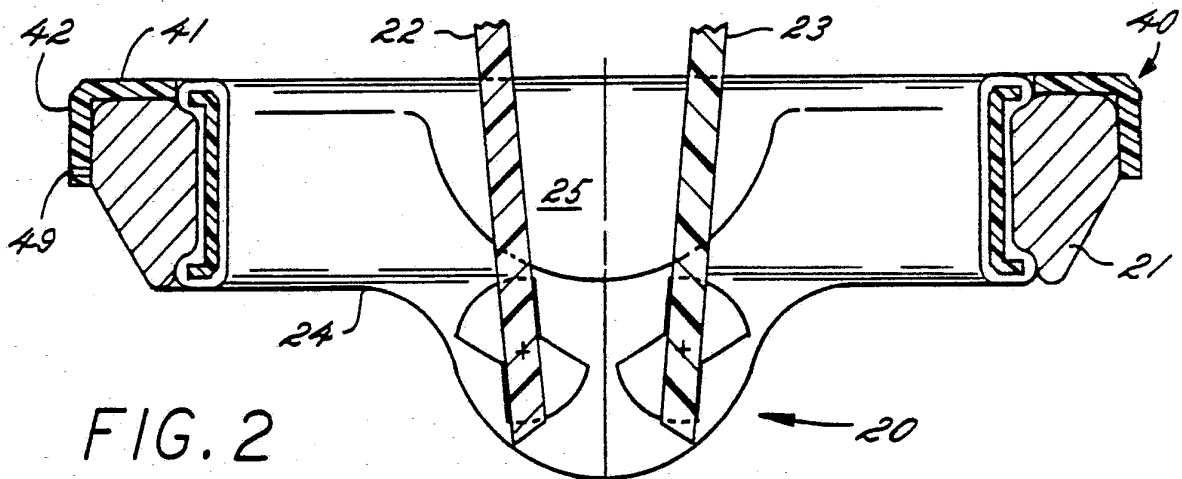


FIG. 2

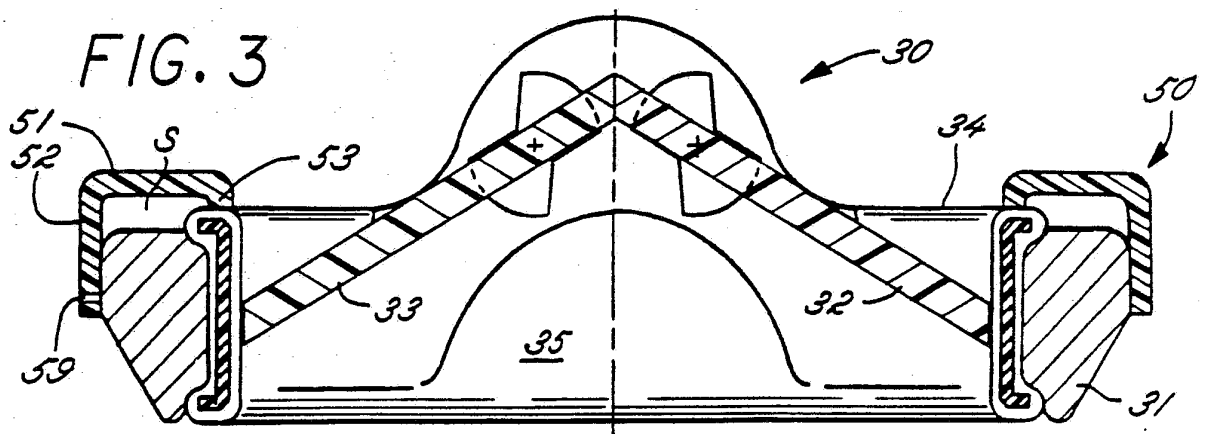


FIG. 3

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US88/02554

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) A61F 2/24 U.S. CL. 623/2		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
US	623/2	
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
Y	US, A, 4,532,659 (KASTER) 06 August 1985 (See column 4, line 68-Col. 5, line 6)	6.5.7.8
X Y	US, A, 4,078,268 (POSSIS) 14 March 1978 (See figure 5, and column 6 lines 53-55)	1-4, 9, 11-13, 15 10
X Y	US, A, 4,364,126 (ROSEN) 21 December 1982 (See figure 4 and column 3, lines 14-19)	1, 5, 13-15 8
* Special categories of cited documents: ¹⁰ "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. "&" document member of the same patent family		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search		Date of Mailing of this International Search Report
31 August 1988		22 NOV 1988
International Searching Authority		Signature of Authorized Officer
ISA/US		James Prizant