

[54] CATHETER INTRODUCTION SYSTEM

[75] Inventors: Martin Monestere, Jr., Lebanon;
Frederick Prunier, West Orange,
both of N.J.

[73] Assignee: C. R. Bard, Inc., Murray Hill, N.J.

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[52] U.S. Cl. 128/214.4, 128/DIG. 16, 128/347,
128/349

[51] Int. Cl. A61m 5/00

[58] Field of Search 128/214.4, 347, 221,
128/349, DIG. 16

[56] References Cited

UNITED STATES PATENTS

3,599,637	8/1971	Schwartz.....	128/214 H
3,547,119	12/1970	Hall	128/214 H
3,225,762	12/1965	Guttman.....	128/214 H
3,313,299	4/1967	Spademan.....	128/214 H
3,297,030	1/1967	Czorny et al.	128/214 H
3,348,544	10/1967	Braun	128/214 H
3,399,674	9/1968	Pannier et al.	128/214 H
3,459,184	8/1969	Ring.....	128/214 H
3,585,996	6/1971	Reynolds	128/214 H

Primary Examiner—Aldrich F. Medbery

Attorney—W. Saxton Seward

[57]

ABSTRACT

A needle and catheter combination for intravenous or supra-pubic use wherein a plastic catheter is mounted on a connector assembly including a first hub which is connected to a second hub by means of a short rubber tube adapted to be bent laterally and to be resealably punctured by a needle (having a hub and a plug) which extends initially through the first hub and catheter with its point projecting from the distal end of the latter. After introduction (e.g. venipuncture) the needle is withdrawn leaving the catheter in the vein or other body cavity; the needle hole through the side of the rubber tube closes and the second hub may then serve as an adapter for connection to an infusion set or drainage receptacle, or an elongated second catheter with adapter may be introduced through the connector assembly and catheter. When the second catheter is used the first catheter may be left in place or may be withdrawn to leave only the second catheter in the vein or other cavity. The needle hub may be opened by removing the plug to permit observation of flashback, and the needle may have a lateral opening in register, initially, with the lumen of the rubber tube to permit injection of liquid immediately upon venipuncture, before removal of the needle.

8 Claims, 5 Drawing Figures

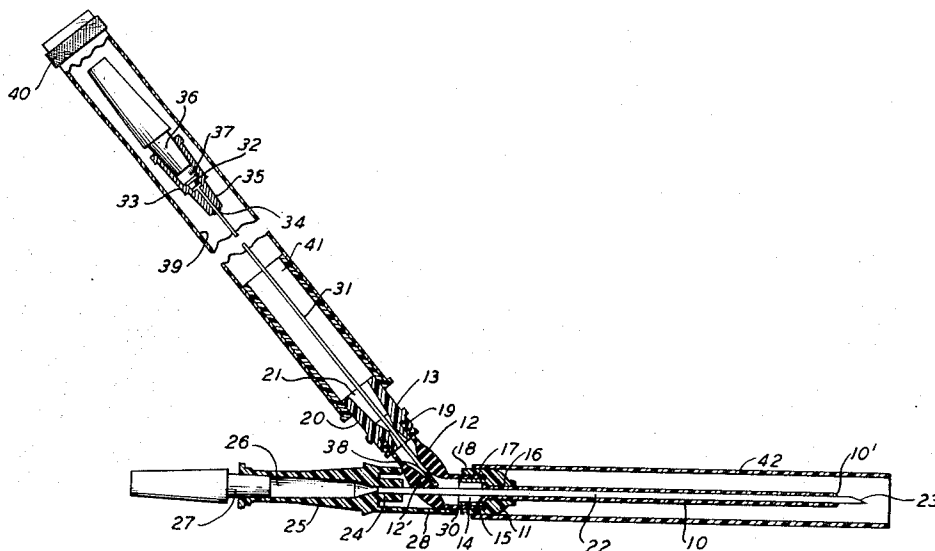


FIG. 2

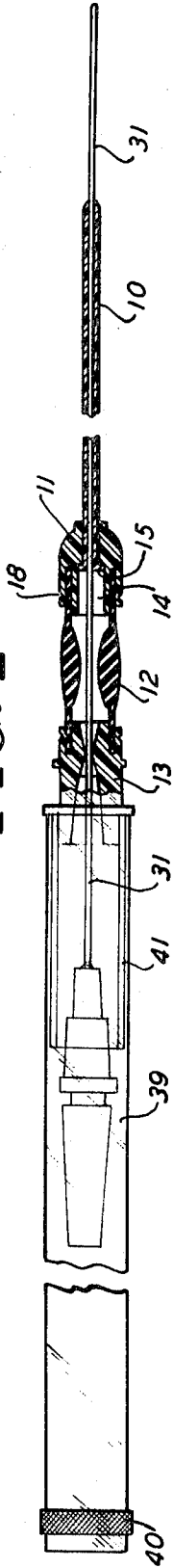


FIG. 3

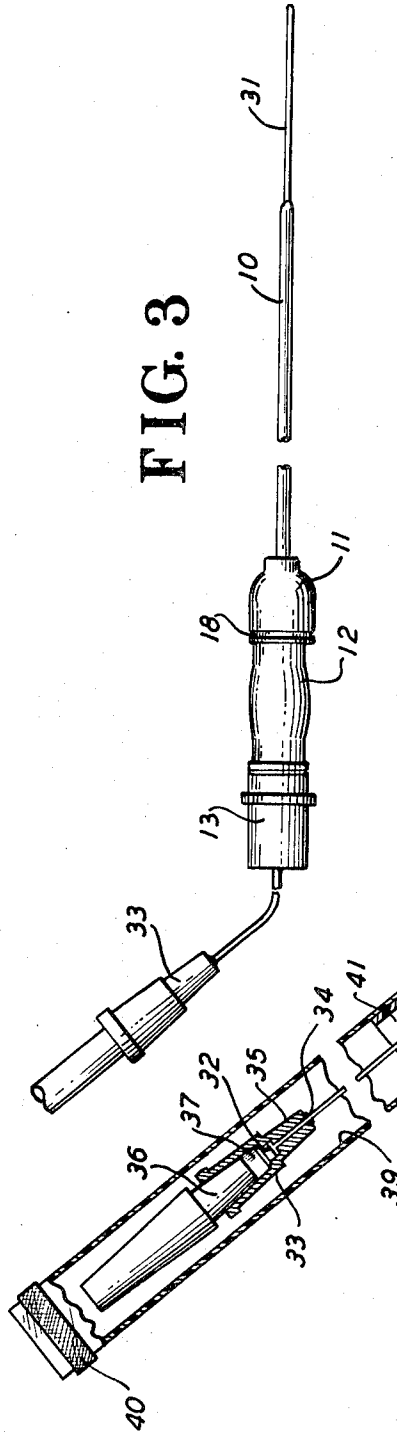
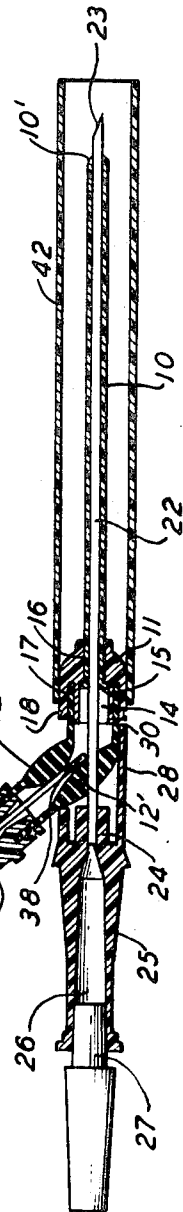


FIG. 1



INVENTORS
MARTIN MONESTERE, JR.
FREDERICK PRUNIER
BY
W. Barton Neward
ATTORNEY

FIG. 4

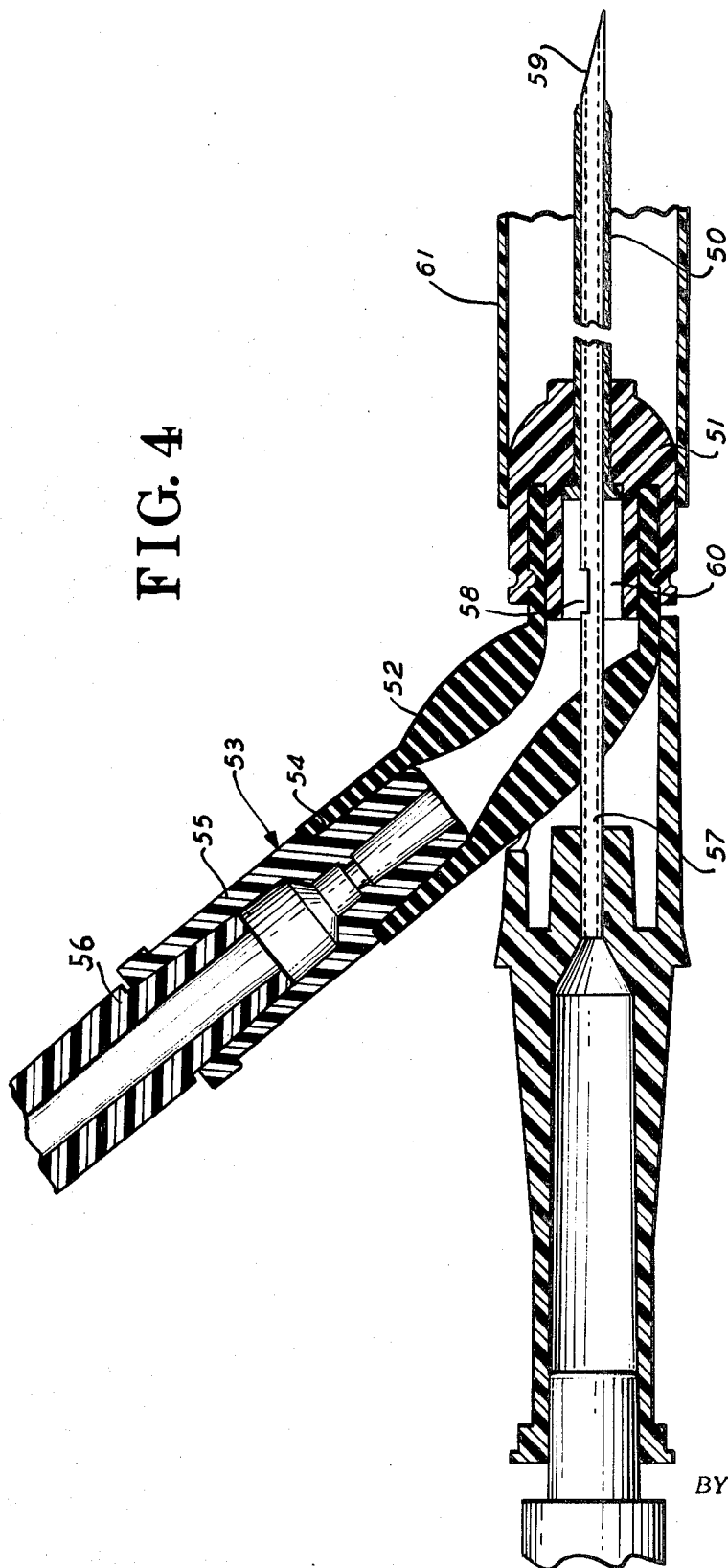
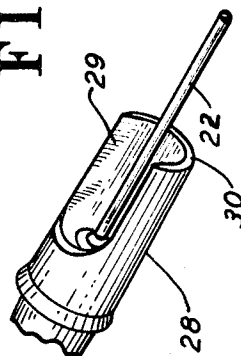


FIG. 5



INVENTORS
MARTIN MONESTERE, JR.
FREDERICK PRUNIER

BY

W. Rayton Newark
ATTORNEY

CATHETER INTRODUCTION SYSTEM

The present system, with particular reference to intravenous injection, comprises two main assemblies which are intended to be packaged in combined position, ready for use. One assembly includes a plastic catheter, tapered at its distal end, a plastic catheter hub, a short gum rubber tube and a second hub. The second hub may, in one form, be a connecting hub through which is passed an elongated catheter having its own infusion hub on the proximal end, the connecting hub being shaped to engage the infusion hub when the elongated catheter has been advanced into the vein, and the introducing catheter has been withdrawn. In a second form, the second hub may be itself the infusion hub, adapted to engage a syringe tip or infusion set adapter. In either form a closing plug is usually provided.

The other main assembly includes a needle, a combined needle hub and guide shield, and a closing plug.

As initially combined, the rubber tube is bent laterally, the needle point is passed through the wall of the tube and advanced through the catheter to project beyond the tapered end thereof. The guide shield is cut away on one side (normally corresponding to the bevel side of the needle point) to accommodate the laterally bent tube, the guide being otherwise of a length such that its distal end rests against the catheter hub when the needle is in proper position for venipuncture. In the form which includes an elongated catheter, the latter is enclosed within a protective sleeve attached to a collar for mounting on the connecting hub.

Known I.V. devices which involve, broadly, the insertion of a needle through a self-sealing wall or plug are shown in the U.S. Pat. to Shaw, No. 2,346,334; Eisenstein No. 2,656,835; Gewecke, No. 2,858,200 and Spademan, No. 3,313,299. There is shown in Guttman U.S. Pat. No. 3,225,762 an elongated catheter having a slit near its distal tip through which a stylet may be passed for insertion of the catheter into a vein, the stylet being then removed and the catheter advanced so that the slit is in the vein. An "intravenous catheter assembly" in which the catheter is inserted by means of an internally disposed needle is shown in Hirsch U.S. Pat. No. 3,335,306, in Gauthier & Massa U.S. Pat. No. 3,094,122, and in Braun U.S. Pat. No. 3,348,544, as well as in the report of "Staff Meetings of the Mayo Clinic," July 4, 1951, pages 268-269, "A Plastic Caudal Needle in Sacral Block Anesthesia." The devices disclosed herein embody improvements in simplicity, convenience, safety, and/or adaptability over any of the prior devices.

Practical embodiments of the invention are shown in the accompanying drawings, wherein:

FIG. 1 represents a longitudinal sectional view of a first form of the device in completely assembled position;

FIG. 2 represents an elevation, partly in section, of the catheter assemblies after removal of the needle assembly, and partial advancement of the catheter.

FIG. 3 represents an elevation, parts being broken away, of the assemblies shown in FIG. 2 after removal of the protective sleeve;

FIG. 4 represents a longitudinal section, on a larger scale, of a modified form of the device, ready for use.

FIG. 5 represents a detail perspective view of hub and guide shield portion of the needle assembly.

Referring to FIGS. 1 to 3, the first catheter assembly includes a plastic catheter (or cannula) 10, a catheter hub 11, a short straight gum rubber tube 12 and a second hub 13. The hub 11 may have an enlarged proximal bore portion 14 within which the proximal end of the catheter is beaded, as shown at 15, to provide a mechanical lock which may be supplemented by the epoxy cementing of the catheter in the smaller bore portion 16. The hub 11 has an annular groove 17, radially outward of the bore portion 14, to receive the distal end of the rubber tube 12. The tube end is inserted into the groove 17 and mechanically locked therein by mechanically crimping the wall of the cylindrical outer proximal end of the hub as shown at 18. The second hub 13 has an annular groove 19 in its distal end (within which is crimped the proximal end of the tube 12), a cylindrical outer surface 20, and a tapered recess 21 in its proximal end.

As an alternative, the hubs 11 and/or 13 and tube 12, constituting a connector assembly, can be molded as a one-piece rubber element.

The needle assembly includes a needle 22 of customary form having a beveled tip 23, mounted at its proximal end in the core portion 24 of the combined hub and guide shield. The needle hub portion 25 has an elongated bore 26 which may be closed by a removable plug 27 in a customary manner. The guide shield portion 28 is a hollow cylinder partially cut away on one side to provide an axially extending slot 29 (FIG. 5) wide enough to receive the tube 12 when the latter is bent laterally and pierced by the needle, as shown in FIG. 1. The slot may typically extend through about 150° to 180° of the circumference of the shield (see FIG. 5), and the length of the shield is so related to the length of the needle 22 and catheter 10 that the needle tip 23 projects slightly outward beyond the tapered tip 10' of the catheter when the distal edge 30 of the shield is against or adjacent the end of the hub 11.

The rubber tube 12 is shown as having a substantially thickened midportion 12' to ensure the presence of enough material for reliable self-sealing of the perforation made by the needle, when the needle is withdrawn.

In the combination of FIGS. 1 to 3 the catheter 10 is intended, generally, to serve as an introducer for a smaller elongated catheter 31 which has a beaded proximal end 32 fitted into the infusor hub 33, for security additional to that provided by the epoxy cementing shown at 34. The outer surface 35 of the distal portion of the hub 33 is tapered to fit snugly in the recess 21 of the hub 13. A flow control plug 36 (similar or identical to the plug 27) fits removably in the proximally flaring bore 37 of the hub 33. In its initial position, as packaged, the distal end 38 of the catheter 31 rests within the rubber tube 12 and the greater length of the catheter, with hub 33 and plug 36, is enclosed within a protective sleeve 39, sealed closed at its proximal end 40 and secured at its distal end to a cylindrical collar 41 which has a friction fit on the outer surface 20 of the hub 13. The needle guard 42 may be simply a tube sized to engage frictionally the outer surface of hub 11 and to extend beyond the tip 23 of the needle 22.

To use the combination of FIGS. 1 to 3, the user should prepare the site, remove the needle guard 42, and proceed with venipuncture in the usual manner, holding the needle hub 25. When the blood appears in the needle hub, flow may be halted by pushing the plug 27 into the hub. Holding the needle hub 25 in one hand

and the catheter hub 11 in the other, the introduction catheter may be further inserted by advancing the hub 11 along the needle until the tapered tip of the catheter 10 has reached a desired position in the vein, at which point the catheter is held stationary and the needle withdrawn and discarded. Upon removal of the needle the rubber tube 12 will straighten out, bringing the hubs 11 and 13 substantially in alignment with respect to the axis of the catheter 10 (FIG. 2). To place the catheter 31 in the vein, it is grasped lightly (through the sleeve 39) a short distance from the collar 41 and pushed forward step by step into and through the catheter 10 to a desired distance where it is held by finger pressure while the catheter 10 may be removed from the vein, the puncture site covered and the catheter 31 suitably anchored to the skin. The collar 41 and sleeve 39 are removed and discarded, the surface 35 of hub 33 being seated within the hub 13 and the infusion set (not shown) being connected to the infusion hub 33.

In the modified form of needle-catheter combination shown in FIG. 4, the catheter 50, catheter hub 51 and rubber tube 52 are the same as the catheter 10, hub 11 and tube 12. The hub 53 however, is modified to constitute an infusion hub, its cylindrical distal end portion 54 being cemented within the proximal end of the tube 52 and its proximal end portion 55 having a tapered bore adapted to be closed by a flow control plug (like plugs 27 and 36) or to receive a syringe tip (e.g. Luer) or the adapter fitting 56 of a liquid administration set, as shown.

The needle assembly in FIG. 4 is the same as that shown and described in reference to FIGS. 1-3 except that the wall of the needle 57 is cut away, as shown at 58, on the same side as the heel of the bevel 59 and in such a position that the opening thus formed is within the enlarged proximal bore 60 of the hub 51 when the needle tip is projecting from the tip of the catheter (i.e. in position for venipuncture). With the provision of the opening 58 an I.V. set may be connected to the hub 53 and turned on following initial venipuncture, flow through the needle bore starting immediately and continuing through the catheter 50 with only a momentary interruption as the needle is withdrawn to leave only the catheter in the vein. The needle guard 61 is the same as the needle guard 42.

It will be recognized that the result achieved by the use of the combination just described resembles that of the Hirsch, Gauthier et al. and Braun Patents, cited above, whereas the result of using the combination of FIGS. 1 to 3 more nearly corresponds to that of Doherty U.S. Pat. No. 3,010,453, Doherty and Ballard U.S. Pat. No. 3,017,884 and Ballard U.S. Pat. No. 3,055,361, the means and manner of achieving these results being, in each instance, materially different.

The two-catheter set shown in FIGS. 1 to 3 is adapted, in customary smaller sizes, for use in intravenous injections, as described, and it can also be used, preferably in somewhat larger sizes, for supra-pubic introduction into the bladder in order to provide a drainage means therefor. When a Foley catheter is left in the bladder for long periods of time it has been found that infection may arise in the vicinity of the balloon, whereas drainage devices introduced supra-pubically are relatively free from this difficulty. When the present two-catheter set is used for this latter purpose the introducing catheter 10 is left in place, serving as an access device, while the second catheter projects into

the bladder and hangs down freely to a position where it can serve as a drain. Absent any substantial suction, there is minimal danger of injury to or irritation of the bladder wall. The hub 33 is, in this case, connected to a drainage tube and receptacle, and the needle may be of the trocar type.

The guide shield 28 is a generally desirable feature, but could be omitted, leaving it to the user to be sure that the needle tip projects a proper distance beyond the end of the first catheter to effect venipuncture or other introduction of the combination.

Materials which have been found to be satisfactory for the several parts described above include, without limitation, radiopaque Teflon for the catheters 10, 31 and 50; nylon for the hubs 11, 13, 33, 51 and 53; polyethylene for the plugs 27 and 36, sleeve 39 and collar 41; nylon for the hub and guide shield 25, 28 and stainless steel for the needles 22 and 57.

While the tubes 12 and 52 are described as being of gum rubber, equivalent materials having adequate self-sealing properties may be substituted, if desired.

It will be understood that various changes may be made in the form, construction and arrangement of the several parts without departing from the spirit and scope of the invention, and hence we do not intend to be limited to the details herein shown or described except as the same are included in the claims or may be required by disclosures of the prior art.

What we claim is:

1. A needle and catheter introduction combination comprising a plastic catheter and catheter hub, a connector assembly including a flexible tubular member of self-sealing material and a second hub, the catheter hub being attached at its proximal end to the distal end of said assembly, and a needle having a point adapted to pass through a wall of the flexible member and through the lumen of said catheter to project beyond the catheter tip, the needle being mounted in a needle hub providing positioning means for limiting the relative axial movement of said needle and catheter when the needle is passed through said wall and said lumen.

2. A needle and catheter introduction combination according to claim 1 in which the needle positioning means includes a needle hub and a cylindrical guide shield extending distally from said needle hub, said guide shield being cut away on one side to permit the tube to extend laterally when the needle is passed through said wall and said lumen.

3. A needle and catheter introduction combination according to claim 2 wherein said guide shield is cut away on the side corresponding to the bevel side of the needle point.

4. A needle and catheter introduction combination according to claim 2 wherein the needle is provided with a lateral opening intermediate the needle hub and the needle point.

5. A needle and catheter introduction combination according to claim 4 wherein said lateral opening is on the side corresponding to the bevel side of the needle point.

6. A needle and catheter introduction combination according to claim 1 which includes an elongated second catheter and an infusion hub on the proximal end of said second catheter.

7. A needle and catheter introduction combination according to claim 6 which includes a protective sleeve enclosing said second catheter and hub, and means re-

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movably securing an end of said sleeve to said assembly.

8. A needle and catheter introduction combination according to claim 6 wherein said second catheter is adapted to be advanced through said plastic catheter, 5

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following venipuncture and removal of the needle, and wherein said infusion hub is engageable with the connector assembly when the second catheter is so advanced.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,739,778 Dated June 19, 1973

Inventor(s) Martin Monestere, Jr. and Frederick Prunier

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Abstract, Line 21, "lteral" should read -- lateral --.

Column 1, Line 64, "reprsents" should read -- represents --.

Column 2, Line 56, "witin" should read -- within --.

Column 2, Line 61, "firctionally" should read -- frictionally --.

Column 3, Line 54, "differerent" should read -- different --.

Column 3, Line 67, "introducing" should read -- introducing --.

Column 4, Line 23, "fOrm" should read -- form --.

Column 4, Line 47, "wnen" should read -- when --.

Signed and sealed this 23rd day of April 1974 .

(SEAL)
Attest:

EDWARD M. FLETCHER, JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents