United States Patent [19]

Frank

[11] **3,780,739**

[45] **Dec. 25, 1973**

[54] **DRAINAGE BAG ASSEMBLY WITH FLOW CONTROL FOR BODY FLUIDS**

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[22] Filed: **Dec. 7, 1971**

[21] Appl. No.: **205,687**

[52] **U.S. Cl.** **128/283**
[51] **Int. Cl.** **A61f 5/44**
[58] **Field of Search**..... 128/275, 283, 294–295, 128/DIG. 24

[56] **References Cited**

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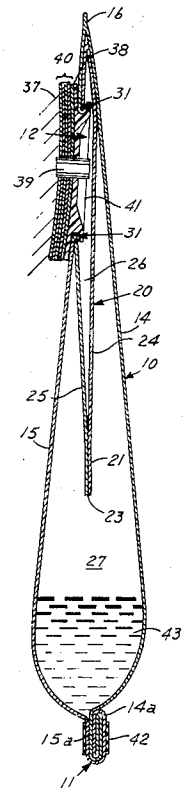
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Primary Examiner—Charles F. Rosenbaum
Attorney—Reilly and Lewis

[57] **ABSTRACT**

A drainage bag assembly for containing body fluids of a patient includes a flat, generally oval-shaped envelope having a lower outlet opening. A receiving opening is located in an upper portion of the envelope which is surrounded by a flexible sealing ring for releasable sealing attachment of the bag to a flanged holder shield secured to the patient's body. An internal flow control valve permits fluid flow received in the receiving opening to pass into a storage chamber in the bottom of the envelope but inhibits reverse back-flow through the valve. In one form an on-off valve controls the discharge of the fluid contained in the envelope through the outlet opening.

14 Claims, 12 Drawing Figures



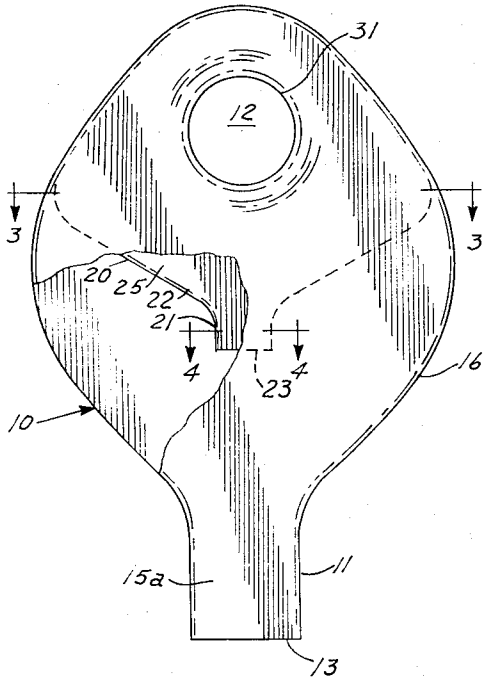


FIG. 1

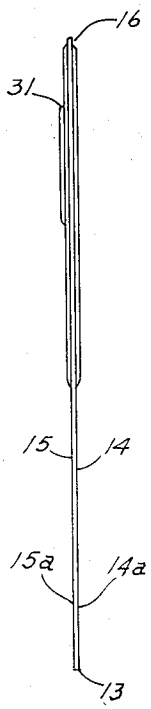


FIG. 2

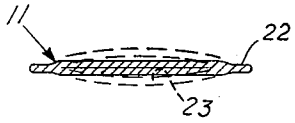


FIG. 4

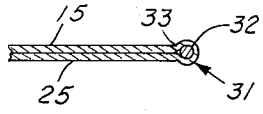


FIG. 6

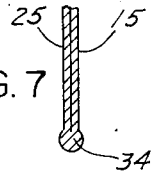


FIG. 7

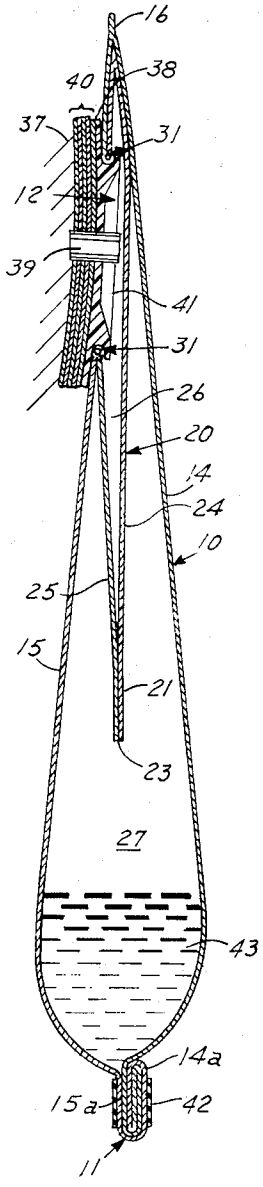


FIG. 8

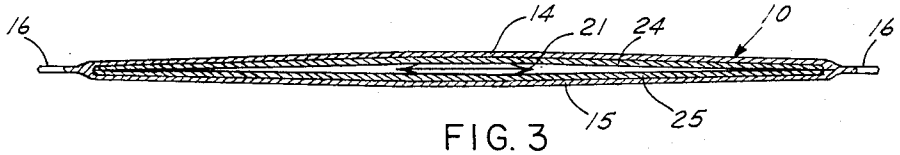
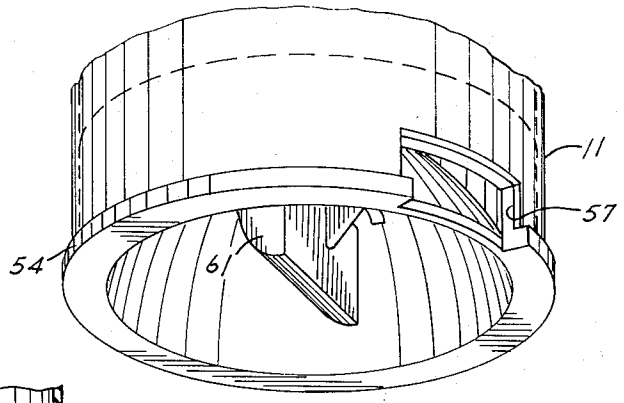


FIG. 3



FIG. 5

FIG. 9



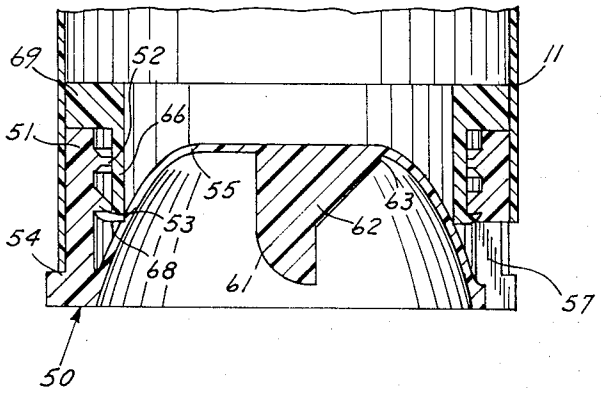
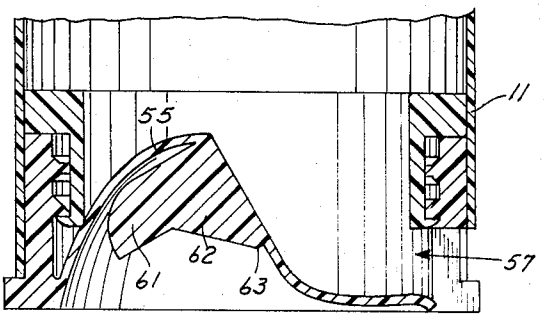


FIG. 10

FIG. 11



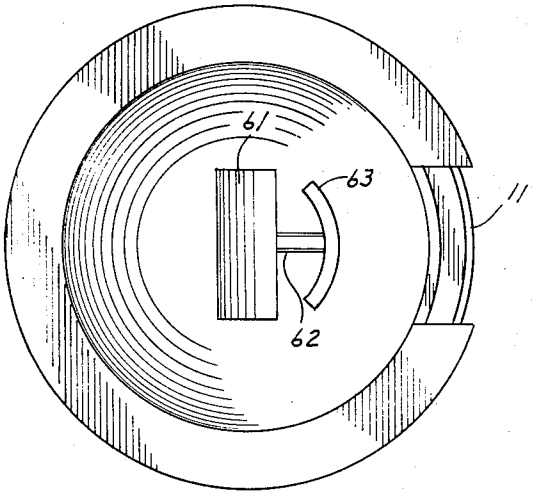


FIG. 12

DRAINAGE BAG ASSEMBLY WITH FLOW CONTROL FOR BODY FLUIDS

This invention in general relates to medical appliances and more particularly to novel and improved drainage bags adapted to be applied to a patient following certain surgical procedures, which bags are particularly suitable for association with a stoma for urinary diversion purposes.

A variety of drainage bags or pouches have heretofore been provided to receive draining body fluids of a patient via the stoma which extends through the outer wall of the abdomen. These bags may also be used for fistulas and to contain drainages from the body due to injuries or tumors. In such devices it is highly desirable to have an effective seal between the holder shield for the bag and the bag to prevent the release of undesirable body odors as well as provide a bag which will readily mount and demount and lie flat or in a flattened condition against the body while containing body fluids so that interference with normal activities is minimized. In the U.S. Pat. No. 3,618,606 issued to R. E. Brown et al entitled STOMA BAG, a drainage bag is attached by means of an internal mounting pad around the inlet opening of the bag to the skin with an adhesive cement. The outlet opening of the bag is held closed by a clip or manual valve.

In my previously filed application Ser. No. 145,386 entitled DRAINAGE BAG HOLDER AND METHOD, there is described a bag holder shield or face plate which is secured directly against the body of the patient and to which a bag made in accordance with the present invention will releasably fasten to be supported from the body of the patient in a dependent and highly effective manner. In the prior art devices the configuration, place of attachment and manner of attachment to the body of the patient have not been entirely satisfactory. Further, no prior devices known utilize an on-off control valve to discharge fluids from the bag.

Accordingly, it is an object of this invention to provide an improved drainage bag assembly for body fluids in the form of a flat outer envelope constructed and arranged to provide an improved balanced weight characteristic while supporting in a dependent manner from the body of a patient and containing a quantity of discharged body fluid.

Yet a further object of this invention is to provide a novel drainage bag assembly for body fluids characterized by an outer envelope having a narrowed lower extension with an outlet opening, an internal unidirectional flow control valve in the envelope, and means for closing the narrowed lower extension to retain the fluid in the envelope.

In accordance with the present invention in the embodiments shown, there is provided a drainage bag assembly including a flat, generally oval-shaped outer envelope having a narrowed, lower extension with an outlet opening. The outer envelope has opposed front and rear walls made of a thin plastic flexible film, preferably transparent for interior inspection. The opposed walls are integrally connected together at their top and side edges but left open at the bottom, to form the drainage outlet with the lower extensions being folded back on itself and the fold secured to close the bottom of the envelope. A rear wall of the envelope has a receiving opening in the upper portion thereof, surrounded by a flexible sealing ring assembly for releasable attachment of and sealed engagement with a flanged part of a

holder shield secured to the body of the patient. An inner envelope divides the envelope into an upper receiving chamber and a lower storage chamber and has a unidirectional flow control valve in the lower portion thereof. The inner envelope is made of a pair of opposed flexible walls of thin plastic film integrally connected together along the side edges and open at the top and bottom. The valve has a flutter-type valve action which opens by the parting of the opposed wall portions to pass fluid downwardly but come together to prevent fluid flowback into the upper chamber. An on-off control valve is disposed in the lower extension of the outer envelope to regulate the drainage of the fluids from the outer envelope.

Other objects, advantages and capabilities of the present invention will become more apparent as the description proceeds taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a rear elevational view of a drainage bag assembly embodying features of the present invention in the flat unfilled condition;

FIG. 2 is a side elevational view of the bag assembly of FIG. 1;

FIG. 3 is a sectional view taken along lines 3—3 of FIG. 1;

FIG. 4 is a sectional view taken along lines 4—4 of FIG. 1 with an open position shown in dashed lines;

FIG. 5 is a bottom plan view of the bag assembly showing the outlet end with an open position in dashed lines;

FIG. 6 is an enlarged sectional view through the flexible sealing ring portion of the bag assembly;

FIG. 7 is a sectional view of an alternative form of flexible sealing ring for securing the drainage bag assembly to the flange of the support shield;

FIG. 8 is a sectional view of the drainage bag assembly shown in FIGS. 1–6 supported on a holder shield attached to the patient and closed at the bottom to contain body fluids;

FIG. 9 is a bottom perspective view of the drainage bag assembly showing an on-off drainage control valve fastened in the lower extension of the outer envelope;

FIG. 10 is a vertical sectional view through the bag assembly and drainage valve shown in FIG. 9 with the valve in a closed position;

FIG. 11 is a vertical sectional view of the assembly shown in FIGS. 9 and 10 with the valve in the open position; and

FIG. 12 is a bottom plan view of the assembly shown in FIGS. 9–11.

Referring now to the drawings, the drainage bag assembly shown comprises a flat, generally oval-shaped, fluid-containing outer envelope **10** having a narrowed lower extension **11** with an upper receiving opening **12** and a bottom outlet opening **13.** The outer envelope **10** with extension **11** is comprised of front and rear flexible walls **14** and **15** connected along their top and side edges having narrowed lower extensions **14*a*** and **15*a***, respectively, which project beyond the oval shape and are connected along their side edges but left open at the bottom edge to define the bottom outlet opening **13.** The lower extension **11** serves as a means of closing the bottom opening to the envelope when folded back on itself as described more fully hereinafter. The envelope **10** with the lower extension **11** is made of a pair of opposed single sheets of thin plastic film and the outer marginal edges along the top and sides are prefer-

ably integrally secured by heat sealing to form an outer unitary bead **16.**

A flat inner envelope **20** having a narrowed funnel-like or downwardly convergent lower extension **21** is disposed in the outer envelope. An upper portion of the inner envelope **20** opens into receiving opening **12** and has a bottom outlet opening **23** at the bottom of the lower extension **21.** The inner envelope **20** is comprised of a pair of opposed front and rear flexible walls **24** and **25** integrally connected along the top and side edges and the extension side edges left open at the bottom to define the outlet opening **23.** The side edges of the upper portion of the inner envelope conform in shape with the upper portion of the oval-shaped outer envelope and are disposed between the front and rear walls **14** and **15** of the outer envelope and are integrally connected at bead **16** with the outer envelope while the side edges of a lower portion and the lower extension are connected along the side edges with a bead **22.** The inner envelope **20** divides the outer envelope **10** into an upper receiving chamber **26** and a lower storage chamber **27.**

Like the outer envelope **10,** the front and rear walls of the inner envelope **20** with the lower extension **21** are made of a pair of opposed unitary thin film sheets. The fluid flow downwardly through the inner envelope **20** parts or spreads the opposed portion of the lower wall extension **21** and comes together in a flutter-like action to prevent backflow into the upper chamber, as best seen in FIG. **4.** In the unfilled condition the walls **14** and **15** and extensions **14***a* and **15***a* lie flat and against the inner envelope **20** and against one another for a very low or thin side profile, as best seen in FIG. **2.**

The receiving opening **12** is surrounded by a flexible attachment ring assembly **31.** The flexible attachment ring structure shown in FIGS. **6** and **8** utilizes a flexible band **32** of circular transverse cross-section which is held in place by folding edges of the rear walls **15** and **25** over the band and heat-sealing at **33** inwardly of the band, leaving enough space for the band to flex within the loop formed by the folded walls to allow the flexible attachment ring to slide over the flange of the holder shield described more fully hereinafter. An alternative arrangement for the flexible band and folded wall edges is to mold an enlarged band **34** of generally circular cross-section at the juncture of aligned openings in the rear walls **15** and **25** of a molded material which is resilient and will flex and contract to embrace and release from the holder shield flange.

The receiving opening **12** is located centrally along the vertical or major axis of the oval shape of the envelope and has its center approximately midway between the center of the oval and the upper edge of the bag, the upper edge of the top of the opening **12** being substantially below the upper edge of the bag. This shape envelope, and its thin film construction, and the location of the receiving opening **12** substantially below the top edge of the bag provides a flat profile and establishes a better balanced weight characteristic in relation to the patient's body as well as having the bag lie generally flat against the patient's body so as to minimize the inconvenience thereof.

Referring now to FIG. **8,** the drainage bag assembly above-described is shown mounted on a patient's body represented at **37** using a holder shield **38** secured to the outer surface of the body with the drainage tube or stoma **39** passing from the body extending through a central opening in the shield, the shield being secured to the body using a liquid seal coating and other layers of materials represented at **40** and as described in more detail in my above referred to copending application and application Ser. No. 130,202 entitled FLEXIBLE FILM-FORMING LIQUID & METHOD FOR APPLYING SURGICAL APPLIANCES. The flexible ring **31** expands over the outer annulus or flange **41** of the holder shield and contracts against the flange and is in a sealed engagement therewith to hold the bag in a dependent manner from the body.

To close the bottom of the outer envelope **10** the lower drainage section **11** may be folded back on itself one or more times and is secured by means of a strip of tape **42** as shown or may be secured by a rubber-coated paper clip or the like. Body fluids **43** are shown contained in the outer envelope **10** in FIG. **8.** In use, once the body fluids **43** are received into the bag through the stoma, they pass through the narrowed lower section **21** by spreading or parting the narrowed opposed wall portions, but the wall portions come back together to prevent backflow or a return flow to the area of the stoma, such as when the patient is in a prone position.

Referring now to FIGS. **9–12,** there is shown an on-off control valve mounted in the lower end of the narrowed lower extension **11** to close the lower end of the outer envelope and allow selected removal of the body fluids **43** therefrom. The control valve includes an integral outer body **50** having a hollow housing portion **51** of circular transverse cross section. The housing **50** has spaced upper and lower inwardly projecting annular ribs **52** and **53,** respectively, a lower, outwardly projecting annular flange portion **54** and an upwardly concave, dome or cup-shaped resilient diaphragm **55** traversing the lower end of the body portion and extending inwardly and upwardly from the inner bottom edge of the lower end of the body portion. An outlet opening **57** of limited circumferential width relative to the entire circumference of the housing portion **51** is provided in a side of the body **50.** The diaphragm portion **55** has a depending section **61,** an arcuate section **63** of limited circumferential extent and a radial section **62** connected between the depending section **61** and arcuate section **63.**

An inner ring **66** made as a separate part from that of the outer body **50** has a lower portion which nests or telescopes therein and has an outwardly extending lower annular rib **68** and an outwardly extending upper annular flange **69.** The inner lower corner edge of the inner ring **66** bears against the outer surface of the cap portion to normally close the valve, as shown in FIG. **10.**

In the operation of the valve, movement of the depending section **61** to one side causes a limited width of the dome concave portion to flex downwardly to move the valve to the open position and release of the forces applied to the depending section **61** allows the diaphragm to move back to the closed position.

The outer integral body **50** is made of a resilient, relatively soft elastomeric material which may be shaped in a mold. The inner ring **66** is made of a harder more rigid plastic material which also may be shaped in a mold. The bag assembly is made of a thin plastic film such as polyethylene. A typical bag assembly will have a material thickness of 4 mil for the inner envelope **20**

and a material thickness of 8 mil for the outer envelope 10. The film may be either transparent or opaque.

Although the present invention has been described with a certain degree of particularity, it is understood that the present disclosure has been made by way of example and that changes in details of structure may be made without departing from the spirit thereof.

What is claimed is:

1. A drainage bag assembly adapted to contain body wastes received from the body of a patient, said bag comprising an outer envelope having a lower outlet opening and a receiving opening in an upper portion adapted to pass body wastes thereinto, and valve means for closing the outlet opening of the envelope to retain the wastes in said envelope, said valve means including a diaphragm traversing the lower outlet opening being biased to a position normally closing the opening and means for selectively flexing the diaphragm to an open position for removal of wastes from said envelope.

2. A drainage bag assembly as set forth in claim 1 wherein said outer envelope is generally oval-shaped.

3. A drainage bag assembly as set forth in claim 2 wherein the longest dimension of the outer envelope is adapted to extend downwardly in a dependent manner from the body of the patient.

4. A drainage bag assembly as set forth in claim 1 including an inner envelope disposed within said outer envelope having front and rear walls connected along their outer top and side edges and having a downwardly convergent lower extension with opposed wall portions normally held flat against one another to define unidirectional flow means, there being an outlet opening along the bottom edge of said downwardly convergent lower extension of said inner envelope.

5. A drainage bag assembly as set forth in claim 4 wherein said outer and inner envelopes are composed of a thin film plastic material.

6. A drainage bag assembly as set forth in claim 1 wherein said outer envelope is transparent to permit visual inspection of the waste material contained therein.

7. A flexible drainage bag assembly adapted to contain a fluid received from the body of a patient, said bag assembly comprising an outer envelope having a narrowed lower extension with a bottom outlet opening, said outer envelope having a receiving opening in an upper portion adapted to pass body fluids thereinto, an inner envelope including unidirectional flow control means disposed in the outer envelope between the receiving opening and the outlet opening and arranged to divide the outer envelope into an upper receiving chamber and a lower storage chamber, said unidirectional flow control means permitting fluid flow delivered into said inlet opening into said lower storage chamber but inhibiting flow from the lower storage chamber back to the receiving opening, and valve means in the form of an upwardly concave resilient diaphragm traversing the outlet opening of the outer envelope and biased to a closed position across the outlet opening to retain the body fluids in the lower storage chamber of said outer envelope.

8. A flexible drainage bag assembly as set forth in claim 7 wherein said valve means includes an integral outer hollow body having an opening, said resilient diaphragm traversing the lower end of the body, said body having an outlet opening in a side thereof, and an inner ring in the body adjacent to the outlet opening having an edge normally in engagement with the diaphragm to close off flow through the outlet opening, said diaphragm being selectively movable away from the inner ring to pass the body fluids contained in the outer envelope through said outlet opening.

9. A flexible drainage bag assembly as set forth in claim 8 wherein said diaphragm has a downwardly depending section, an arcuate section aligned with the outlet opening and a section connecting the depending and arcuate sections for the movement of the diaphragm to the open position.

10. A flexible drainage bag assembly adapted to be releasably mounted on a flanged holder shield positioned on the body of a patient comprising:

a pair of first, generally oval-shaped front and rear walls connected at their outer edges along the top and side edge to define an outer fluid-containing envelope, said outer envelope having a narrowed lower extension with a bottom outlet opening, said rear wall having a receiving opening in an upper portion surrounded by a flexible sealing ring assembly adapted to releasably engage the flange of the holder shield in a sealed engagement to receive body fluids therethrough,

a pair of second front and rear walls disposed within said outer envelope and connected at their outer edges along the top and side edges to define an inner envelope within said inner envelope and dividing the outer envelope into an upper receiving chamber and a lower storage chamber, said inner envelope having a downwardly convergent lower extension with a bottom opening defining a unidirectional flow control valve permitting fluid flow delivered into said receiving opening into said lower storage chamber but inhibiting fluid flow from the lower storage chamber back into the upper receiving chamber, the rear wall of said inner envelope being joined to the rear wall of said outer envelope to define a common peripheral edge of the receiving opening, and

a resilient reinforcing ring disposed at the common peripheral edge of the opening adapted to be releasably mounted in an annular groove on the holder shield.

11. A flexible drainage bag assembly as set forth in claim 10 wherein said receiving opening has its center approximately midway between the center of the oval shape and the upper edge of the envelope, the receiving opening terminating below said upper edge.

12. A drainage bag assembly as set forth in claim 10 wherein said closing means for the outlet opening of the envelope includes a narrow lower extension projecting downwardly from the bottom of the envelope and folded back on itself, and means to retain the lower extension in the folded position.

13. A drainage bag assembly as set forth in claim 10 wherein said resilient reinforcing ring is in the form of a flexible O-ring interposed between the inner peripheral edges of the inner and outer envelopes.

14. A drainage bag assembly as set forth in claim 10 wherein said resilient reinforcing ring is defined by a resilient band made integral with the outer envelope.

* * * * *

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,780,739 Dated 25 December 1973

Inventor(s) Mathilda C. Frank

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

In the Specification:

Column 1, line 23, cancel "internal" and substitute -- integral --

In the Claims:

Column 5, line 38, cancel "set forth in Claim 1" and substitute -- set forth in Claim 10 --

Signed and sealed this 9th day of April 1974.

(SEAL)
Attest:

EDWARD M.FLETCHER,JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents