(54) Title: TOXICITY RESISTANT TAMNON STRUCTURE

(57) Abstract

The tampon structure combination (10) comprises a first structure including a flexible receptacle (14) for receiving menstrual flow upon exposure to the cervix (20) and a second structure (25a, 25b, 25c) connected to the first structure for allowing closing of the first structure, and for retracting the tampon structure in response to pulling force application to the second structure.

With international search report.
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>AT</td>
<td>Austria</td>
<td>GB</td>
<td>United Kingdom</td>
<td>MR</td>
<td>Mauritania</td>
</tr>
<tr>
<td>AU</td>
<td>Australia</td>
<td>GE</td>
<td>Georgia</td>
<td>MW</td>
<td>Malawi</td>
</tr>
<tr>
<td>BB</td>
<td>Barbados</td>
<td>GN</td>
<td>Guinea</td>
<td>NE</td>
<td>Niger</td>
</tr>
<tr>
<td>BE</td>
<td>Belgium</td>
<td>GR</td>
<td>Greece</td>
<td>NL</td>
<td>Netherlands</td>
</tr>
<tr>
<td>BF</td>
<td>Burkina Faso</td>
<td>HU</td>
<td>Hungary</td>
<td>NO</td>
<td>Norway</td>
</tr>
<tr>
<td>BG</td>
<td>Bulgaria</td>
<td>IE</td>
<td>Ireland</td>
<td>NZ</td>
<td>New Zealand</td>
</tr>
<tr>
<td>BJ</td>
<td>Benin</td>
<td>IT</td>
<td>Italy</td>
<td>PL</td>
<td>Poland</td>
</tr>
<tr>
<td>BR</td>
<td>Brazil</td>
<td>JP</td>
<td>Japan</td>
<td>PT</td>
<td>Portugal</td>
</tr>
<tr>
<td>BY</td>
<td>Belarus</td>
<td>KE</td>
<td>Kenya</td>
<td>RO</td>
<td>Romania</td>
</tr>
<tr>
<td>CA</td>
<td>Canada</td>
<td>KG</td>
<td>Kyrgyzstan</td>
<td>RU</td>
<td>Russian Federation</td>
</tr>
<tr>
<td>CF</td>
<td>Central African Republic</td>
<td>KP</td>
<td>Democratic People's Republic of Korea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CG</td>
<td>Congo</td>
<td>CI</td>
<td>Côte d'Ivoire</td>
<td>SD</td>
<td>Sudan</td>
</tr>
<tr>
<td>CH</td>
<td>Switzerland</td>
<td>CM</td>
<td>Cameroon</td>
<td>SE</td>
<td>Sweden</td>
</tr>
<tr>
<td>CI</td>
<td>Côte d'Ivoire</td>
<td>CN</td>
<td>China</td>
<td>SI</td>
<td>Slovenia</td>
</tr>
<tr>
<td>CS</td>
<td>Czechoslovakia</td>
<td>CZ</td>
<td>Czech Republic</td>
<td>SK</td>
<td>Slovakia</td>
</tr>
<tr>
<td>DE</td>
<td>Germany</td>
<td>DK</td>
<td>Denmark</td>
<td>SN</td>
<td>Senegal</td>
</tr>
<tr>
<td>ES</td>
<td>Spain</td>
<td>FI</td>
<td>Finland</td>
<td>TD</td>
<td>Chad</td>
</tr>
<tr>
<td>FR</td>
<td>France</td>
<td>GA</td>
<td>Gabon</td>
<td>TG</td>
<td>Togo</td>
</tr>
<tr>
<td>TR</td>
<td>Turkey</td>
<td>MN</td>
<td>Mongolia</td>
<td>TJ</td>
<td>Tajikistan</td>
</tr>
<tr>
<td>TT</td>
<td>Trinidad and Tobago</td>
<td></td>
<td></td>
<td>UA</td>
<td>Ukraine</td>
</tr>
<tr>
<td>US</td>
<td>United States of America</td>
<td></td>
<td></td>
<td>UE</td>
<td>United States of America</td>
</tr>
<tr>
<td>UZ</td>
<td>Uzbekistan</td>
<td>VN</td>
<td>Viet Nam</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
TOXICITY RESISTANT TAMПON STRUCTURE

BACKGROUND OF THE INVENTION

This application is a continuation-in-part of Serial No. 08/228,503 filed April 15, 1994, which is a continuation-in-part of Serial No. 08/002,642 filed January 11, 1993, now U.S. Patent 5,342,331, issued August 30, 1994.

This invention relates generally to flow-controlling tampons, and more specifically to an improved tampon which controls and collects menstrual flow in such manner as to prevent toxic reaction.

In the past, flow collection tampons were found to be objectionable due to toxic reaction, as at tissue surfaces contacted by the collecting flow or substances over periods of time. Also, prior tampons were found objectionable due to flow leakage and contact with the user's hands, as during tampon removal.

There is need for improved tampon apparatus overcoming the above problems and difficulties, as well as providing additional and improved structural and functional features, as well as enhanced or better results, including protection and comfort in use.

SUMMARY OF THE INVENTION

It is a major object to provide improved tampon apparatus which meets the above needs, by having no moisture absorbent area in direct contact with the user's body or mucosal membranes.

Basically, the flow-controlling tampon of the
present invention comprises a flow-controlling tampon, comprising, in combination:

a) a generally upright, tube having upper and lower ends, and a plunger within said tube and manipulable proximate the tube lower end,

b) flow receiving means positioned within the tube to be bodily displaced and to protrude from said upper end of the tube in response to said manipulation of the plunger,

c) said flow receiving means having an upper end portion configured to expand to fit over the cervix in response to upward bodily displacement of said flow receiving means effected by the plunger,

d) and removal means associated with said upper end portion of said receiving means to effect contraction thereof when said flow receiving means is withdrawn away from the cervix.

As will be seen, the flow receiving means may include a thin sheath typically extending about flow absorbent material, which is non-absorbent to said flow.

Another object is the provision of the expandable upper end of the flow receiving means to have cup shape, as when expanded. The cup may have funnel or scroll shape, or other shape allowing for expansion and contraction. Also, the flow absorbent material is typically fibrous and extends within the sheath to wick fluid upwardly, after flow down a central tube that receives flow from the upper cup.

A further object includes provision of the removal means to include a collapsible element interfitting the upper end portion of the flow receiving means. As will be seen, the collapsing element may include a string or flexible strand or strands to be pulled by force exerted during withdrawal of the flow absorbent means away from the cervix; and in this regard the pull strand may extend downwardly adjacent the flow.
absorbent means and away from said upper end portion of the sheath.

Yet another object includes the provision of lateral strands attached to said sheath upper portion, a main strand extending downwardly past the flow absorbent material, and a connection connecting said main strand and lateral strands. A pusher may be associated with said removal means to create withdrawal force pushing downwardly on the device when said removal means is displaced downwardly, manually, for extracting said tampon. The pusher is typically located to create such withdrawal force in conjunction with strand operation to at least partly close the flow collecting cup or sheath upper portion, as over a flow receiving pocket.

A further object includes the provision of a tampon device comprising:

a) flow receiving means adapted to be displaced toward the cervix,

b) said flow receiving means including a moisture resistant sheath structure having an expansible upper portion to extend about the cervix, and also including flow absorbent material within the sheath structure,

c) removal means associated with said upper end portion for collapsing same when the flow receiving means is withdrawn away from the cervix.

A further object is to provide a toxicity resistant device which has no moisture absorbent area in direct contact with the user's body or mucosal membranes.

Another object is to provide a flow-receiving means or receptacle having a deployable portion configured to distend from a downward collapsed position to an upwardly deployed condition, to extend into engagement with vaginal walls associated with the cervix, and accommodation to length of vaginal barrel, following its being expelled from the tube,
and removal means associated with the receiving means to
effect withdrawal thereof away from the cervix, whereby upper
extent of the deployable portion of the flow-receiving means
gathers to retain flow in the flow-receiving means during
withdrawal.

As will be seen, the flow-receiving means typically
comprises a flexible film receptacle opening upwardly toward
the cervix and having a flexible wall defining the deployable
portion. In one form of the invention, the flexible wall
defines annular corrugations which are self-expandable,
upwardly, in conjunction with the flexible wall being expelled
from the tube.

It is another object of the invention to provide the
deployable portion of the flow-receiving means with terminals
which self-interengage when gathered to retain flow in the
flow-receiving means during withdrawal.

A further object is to provide a flow-receiving
means which includes a sleeve carrying the flow receptacle.
The sleeve may incorporate structure which urges the flexible
wall of the receptacle into deployed condition, after or as
the sleeve and flexible wall emerge from the insertion tube.
Such structure may include multiple memory arms self-
deployable in bending mode from downwardly collapsed
positions, in which the flexible wall of the receptacle fits
over the arms, to self-urged, progressively upwardly, deployed
position, in which the flexible wall is urged adjacent vaginal
walls.

Yet another object is to provide such structure, as
for example memory arms, to have an upwardly, finally deployed
position in which the flexible wall is gathered to isolate
flow received in the flow-receiving, flexible, film receptacle
during withdrawal. The arms are typically folded back
downwardly alongside the sleeve in collapsed position;
whereas, the arms project in cantilevered condition from and above the sleeve in the finally deployed position. Further, the arms typically had distal end portions that are self- urged toward one another in finally deployed position.

These and other objects and advantages of the invention, as well as the details of an illustrative embodiment, will be more fully understood from the following specification and drawings, in which:

DRAWING DESCRIPTION

Fig. 1 is an elevation in section, to show one form of the invention, prior to expansion of the upper end of flow receiving means;

Fig. 2 is a view like Fig. 1 showing expansion of the upper end of the flow receiving means, to extend about the cervix, as during insertion;

Fig. 2a is an elevation showing a modified device;

Fig. 3 is a view like Fig. 1, but showing the device during withdrawal away from the cervix;

Fig. 4 is a section taken on lines 4-4 of Fig. 1;

Fig. 5 is a section taken on lines 5-5 of Fig. 3;

and

Fig. 6 is a view showing a scroll form of expansible flow absorption means:

Fig. 7 is a vertical section showing an as-molded condition of a flexible, generally tubular, flow-receiving means;

Fig. 7a is a section on lines 7a-7a of Fig. 1;

Fig. 8 is like Fig. 7 but shows upper extent of the device being turned back downwardly, annularly;

Fig. 9 shows completion of down-turning of the device upper portion, whereby the lower receptacle portion is
effectively re-entrant into the device upper portion;

Fig. 10 is like Fig. 9 but shows the re-entrant device installed in an insertion tube;

Fig. 11 is like Fig. 9 and shows the device inserted into the vagina;

Fig. 12 is like Fig. 11 but shows the device emergent from the downwardly removed insertion tube, with upper extent of the device deployed outwardly by sleeve arms to engage vaginal walls;

Fig. 13 is like Fig. 12 but shows the lower receptacle portion of the flow-receiving device displaced downwardly, and the upper extent of the device collapsing beneath the cervix;

Fig. 14 shows the device being withdrawn from the vagina, the upper extent of the device self-collapsed to retain collected flow isolated in the device interior;

Fig. 14a is a section taken on lines 14a-14a of Fig. 14;

Fig. 15 is a view like Fig. 14 showing a modified device;

Fig. 16 is a view like Fig. 11 showing the modified device emerging from the insertion tube;

Fig. 17 is a view like Fig. 12 showing the Fig. 15 device self-deployed outwardly, no sleeve arms being used;

Fig. 18 is a view like Fig. 17 showing a further stage of deployment, the insertion tube having been withdrawn;

Fig. 19 is a view like Fig. 13, the lower extent of the Fig. 15 device being withdrawn downwardly; and

Fig. 20 is a view like Fig. 14 showing the Fig. 15 device with its upper extent self-collapsed to retain collected flow isolated in the device interior.
DETAILED DESCRIPTION

Fig. 1 shows a generally upright applicator tube 10 having an open upper end at 11 and an open lower end 12. The tube consists of fluid impervious plastic material, that prevents fluid passage through the tube wall. The tube is relatively stiff and non-collapsible enabling ready insertion within the vaginal passage.

Received within the tube is flow receiving means indicated at 14, to be bodily endwise displaced within and from the tube upper end. A plunger 16 within the tube and beneath the means 14 is adapted to be pushed upwardly via a stem 17, to expel the flow receiving means 14 endwise upwardly as referred to, after which the plunger and stem are retrieved. The flow receiving means includes a thin sheath 18 that extends about flow absorbing means 15, the sheath being impervious to moisture, whereby it does not collect moisture within the sheath wall, during use. The sheath may for example consist of latex.

The flow absorbing material 15 may be fibrous and packed together to form a fibrous body within the sheath. It has an upper end portion 15a just below the sheath upper end portion 18a, to be displaced from the tube 10, as effected by the plunger. Note also expansion of the sheath upper portion 18a to extend about the cervix 20. Fig. 2 shows this condition, with self-expanded wall bending upwardly and outwardly to encompass or bound the cervix when placed in position, by the plunger. The sheath may have "memory" to expand outwardly, as it is pushed out the upper end of the tube. Other modes of expansion are also possible, as for example outwardly expanded petals. Material 15 may have the same or similar composition as is used in conventional tampons.
The flow receiving means 14 is adapted to be readily removed, and also at least partially closed, upon manipulation of removal means associated with upper end portion or portions of 18, whereby the received flow is contained and held, i.e. not uncontrollably spilled. In Figs. 1-4, the removal means takes the form of a string or flexible strand having a lower main strand section 25a, and upper strand sections 25b connected at 25c to 25a. The strand sections 25b are attached to the cup or cup sections 18b (if used) at or near their upper ends, and in such manner that when pulled, the strands 25a and 25b pull the cup sections toward one another to close the cup (see Fig. 3), thereby closing off the upper interior of the flow receiving sheath 18. Note flow receiving pocket 50 above material 15 to prevent fluid spillage upon retraction of the device away from the cervix. Note pull string section 25a extending downwardly alongside or through the absorbent material 15. Strand sections 25b are collapsed in Fig. 1, and extended in Fig. 2. Fig. 4 shows strand connections at 25d to uppermost extents of cup sections 18a. Pulling of string section 25a pulls the sections of the cup together with bowing as they are pulled downward, closing the pocket 50. See bowed extents 18e in Fig. 3. Such bowed extents can be pulled down into an inner flow tube 60, and in particular into the upper flared extent 60a of tube 60 (see Fig. 3). Note in Fig. 6 the alternative collapsible scroll shape of the collector 180 (substituted for 18a).

The connection or knot 25g acts as a pusher, to push downward as seen in Fig. 3, to create withdrawal force to pull the tampon away from the cervix, during removal, in response to finger pulling downwardly on string 25a. Therefore the strands have the dual function of closing of the tampon pocket 50, as well as tampon removal, to prevent fluid spillage. The
non-moisture absorbent quality of sheath 18 prevents toxicity, that might result from direct contact of fluid absorbent material with vaginal wall tissue.

Knot 25c may engage an annular obstruction 62 in tube 60, to create the downward force referred to. See Fig. 3. Tube 60 receives the flow from cup 18a, via a screen 63 extending across the upper flared extent 60a of tube 60. Flow clots are retained above that screen. Flow passing downwardly in inner tube 60 is then passed outwardly via perforations 63, to wick upwardly in material 15, about inner tube 60, but within the sheath 18. The sheath lower end may be closed, at 15, as seen in Fig. 3. Fig. 3 also shows sheath retention in vaginal wall 66.

In Fig. 2a, the cup 18a' is angled relative to sheath 18', to conform more naturally to the anatomy.

The cup 18 may consist of biodegradable latex. The absorbent material may consist of a material such as laminaria hyperboria that forms a gel on aqueous flow contact.

As described this invention provides a device which has no moisture absorbent area in direct contact with the user's body or mucosal membranes.

In Fig. 7, the flow receptor or receiving means 110 comprises an elastomeric film, such as latex, forming a flaccid, tubular body 111 having a receptacle-shaped lower portion, with a tubular wall 111a and bottom wall 111b. The upper walled extent 111c in as-molded condition, as shown, is to be closed together or gathered.

Fig. 7a shows upper extent 111c having overlapping leaves 111d. Flow-absorbing or wicking material 112 is introduced into the interior of the lower portion of the device, to receive menstrual flow. A semi-rigid, plastic or elastomer sleeve 113 has a tubular body with side wall 114 and
lower wall 115 forming a receptacle. The sleeve has structure, such as cantilever arms 116, projecting upwardly, and tapering inwardly at 116a, in as-molded condition. The arms always seek that position, despite being bent downward, as in Figs. 8-12. Sleeve 113 carries within it the flaccid film receptacle 111a and 111b elements.

During assembly, the arms 116 are forcibly bent downwardly, as in Figs. 8 and 9; and the flow-receiving film upper portion 111c is draped over the arm bends at 116b, to hang downwardly, as facilitated by their leaf structure seen in Fig. 7a. Such an assembly of 110 and 113 is assembled into the insertion tube 118, above a pusher 119, as in Fig. 10, that tube blocking radially outward movement of bent arms 116 seeking to restore to Fig. 7 position. Receptor portion 111d is thus re-entrant into 111c, which hangs as a skirt outside arms 116.

In use, the assembly of 110, 113 and 118 is inserted into the vagina, as indicated at 120 in Fig. 11, in alignment with the cervix 121. The pusher 119 is then manipulated to push the assembly of 110 and 113 relatively upwardly, and the tube 118 is withdrawn downwardly. As a result, the bent arms 116 are free to move radially outward, as they seek to restore to Fig. 7 position. The downwardly hanging upper extent 111c of the flow-receiving device 111 is thereby urged outwardly into sealing engagement with vaginal walls, as at loci 123 in Fig. 12, to stabilize the position of the assembly in the vaginal cavity 125, and sealing off the flow so that it enters the interior 126 of the receptor portion 111a via the cup-shaped upper extent 111c of the receptor. See arrows 127 in Fig. 12.

Fig. 13 shows the arms 116 substantially unbent and self-restored upwardly, as the assembly of 110 and 113 is initially withdrawn downwardly, as by partially pulling on a
string 130 attached to 110 and/or 113. The arms 116 deflect the upper film portion 111g of the flow-receiving means 111, as shown, maintaining it in sealing contact with vaginal walls, as at loci 123a, closer to the cervix. Flow continues to be received downwardly via the reduced entrance 134 to the receptacle 111c, and into the absorbent material seen at 112. See arrows 135.

Fig. 14 shows the assembly 110 and 113 being withdrawn downwardly away from the cervix. This allows arms 116 to self-restore to Fig. 7 position, thereby acting to deflect the upper portion 111g of 111 into gathered and closed position, completely isolating the flow-receiving interior 126 of the receptacle 111. Enlargements 116e molded integrally with the uppermost extents of the arms 116 press inwardly toward one another, closing the material of 111g together at 111g, as seen in Fig. 14a. Accordingly, the tampon or catamenial device may be manually retrieved with minimum finger exposure to menstrual flow, and no such exposure to flow collected in the device.

Referring to Figs. 15-20, the modified device is similar to that of Figs. 7-14; however, elements 110 and 113 of Figs. 1-8 are integrated into one element, which has a self-closing upper position; i.e., need for a separate sleeve with biasing arms 116 is eliminated.

Fig. 15 shows the generally tubular, non-flaccid, thin-walled device 140 having lower, tubular side wall 140a and bottom wall 140b forming a receptacle for menstrual flow. The tubular upper side wall extent 140c defines annular corrugations at 140d which seek to restore from vertically collapsed condition within insertion tube 141, to expanded or extended condition, as seen in Figs. 17 and 18, after tube 141 is withdrawn. Corrugations 140d are "springy" and yieldably resiliently resist compression. The tubular uppermost extent
140e is forcibly and yieldably resiliently turned down in Fig. 15, within tube 141, so that side wall extents 140a and 140c are downwardly re-entrant. Uppermost extent 140e may comprise overlapping leaves, as shown in Fig. 7a in order to maintain tubular configuration when freed and expanded to engage against vaginal walls, as in Figs. 17 and 18.

Fig. 16 shows emergence of the device 140 from the insertion tube, as by pusher 119 manipulation to push 140 upwardly, by engagement with wall 140b.

In Fig. 17, the device 140 has completely emerged, and wall extent 140e seeks to deflect outwardly, into sealing engagement with vaginal walls at loci 144. Also, corrugations 140d expand upwardly, to urge device wall or walls 140e upwardly.

In Fig. 18, the tube 141 has been completely withdrawn. Flow into the device is indicated by arrow 148.

In Fig. 19, partial withdrawal downwardly of the device 140 allows upper extents 140e to maintain sealing engagement, generally annularly, with the vaginal walls at loci 149.

Fig. 20 shows withdrawal of the entire device 140, the walls 140e self-gathering by material memory restoration action, to press together at 150 and close the device, above its flow-collecting interior 151. A withdrawal string appears at 152.

A representative material of device 140 is silicone or latex.
13

CLAIMS

1. In tampon structure the combination comprising:
   a) first means including a flexible receptacle for receiving menstrual flow upon exposure to the cervix, and
   b) second means connected to said first means for allowing closing of said first means and for retracting said tampon structure in response to pulling force application to said second means.

2. The combination of claim 1 including a generally upright insertion tube having upper and lower ends, and a plunger within said tube and manipulable proximate the tube lower end, said receptacle positioned within the tube to be bodily displaced and to protrude from said upper end of the tube in response to said manipulation of the plunger, said flow receiving receptacle having an upper end portion configured to expand to extend about the cervix in response to upward bodily displacement of said flow receiving means effected by the plunger, said second means associated with said upper end portion of said receptacle to effect contraction thereof when said tampon structure is withdrawn away from the cervix.

3. The combination of claim 1 wherein said first means includes flow absorbent material and a thin sheath about said flow absorbent material and which is non-absorbent to said flow.

4. The combination of claim 1 wherein the upper end of said receptacle has cup configuration, when expanded.

5. The combination of claim 2 wherein said receptacle is in collapsed condition prior to said upward bodily displacement thereof.

6. The combination of claim 1 wherein said second means includes flexible strand means to be pulled by force
exerted during withdrawal of said tampon structure away from the cervix.

7. The combination of claim 6 including an enlargement on said strand means to be pulled downwardly and exert downward force on said first means.

8. The combination of claim 3 including an internal tube extending downwardly within said sheath, to receive downward flow from said receptacle, and absorbent material about said internal tube to receive flow therefrom.

9. The combination of claim 2 wherein said receptacle has a deployable portion configured to distend from a downward collapsed position to an upwardly deployed condition, to extend into engagement with vaginal walls associated with the cervix, and accommodation to length of the vaginal barrel, in conjunction with its being expelled from the tube, and second means associated with said receptacle to effect withdrawal thereof away from the cervix, whereby upper extent of the deployable portion of the receptacle gathers to retain flow during said withdrawal.

10. The combination of claim 9 wherein said flow-receiving means includes a flexible film receptacle opening upwardly toward the cervix and having a flexible wall defining said deployable portion.

11. The combination of claim 10 wherein said receptacle has a flexible wall that defines annular corrugations which are self-expandable, upwardly, in conjunction with said receptacle being expelled from the tube, allowing self-fitting of the flexible wall to accommodate to the varying lengths of the vaginal barrel.

12. The combination of claim 11 wherein said first means includes a sleeve carrying said receptacle, there being structure on the sleeve urging the flexible wall of the receptacle into the deployed condition, said receptacle wall
being flaccid.

13. The combination of claim 12 wherein said structure includes multiple memory arms self-deployable in bending mode from downward collapsed positions in which said flexible wall of the receptacle fits over the arms, to self-urged, progressively upwardly deployable positions in which said flexible wall is urged against the vaginal walls.

14. The combination of claim 12 wherein said structure has an upwardly, finally deployed position in which said flexible wall is gathered to isolate flow received in said receptacle during said withdrawal.

15. The combination of claim 13 wherein said arms are folded back downwardly alongside said sleeve in said collapsed positions.

16. The combination of claim 13 wherein said arms project in cantilever condition from and above said sleeve in finally deployed positions and have distal end portions that are self-urged toward one another in finally deployed positions.

17. The combination of claim 13 wherein said arms and sleeve have one-piece molded construction.

18. The combination of claim 9 wherein said deployable portion of the flow-receiving means has terminals which self-interengage when gathered to retain flow in the receptacle during said withdrawal.

19. The combination of claim 2 including a plunger within the insertion tube and manipulable to expel the receptacle from the tube.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) : A61F 13/24
US CL. : 604/330, 904

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 128/769; 604/55, 330, 354, 904

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X, P</td>
<td>US, A, 5,342,331, (SILBER ET AL.), 30 August 1994. See the figures, and column 2 lines 35-37.</td>
<td>1, 3-4, 6-8</td>
</tr>
<tr>
<td>X</td>
<td>US, A, 4,486,191, (JACOBO), 04 December 1984. See the figures.</td>
<td>1-10, 18-19, 11-17</td>
</tr>
</tbody>
</table>

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

Date of the actual completion of the international search: 18 MAY 1995

Date of mailing of the international search report: 07 JUN 1995

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703) 305-3230

Authorized officer: [Signature]
DAVID H. WILLSE
Telephone No. (703) 308-2903

Form PCT/ISA/210 (second sheet)(July 1992)