

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
21 November 2002 (21.11.2002)

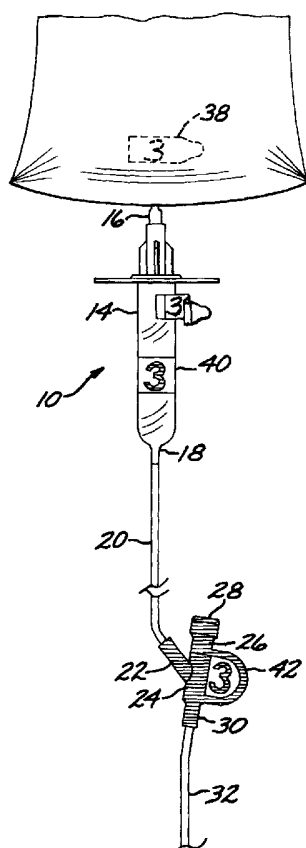
PCT

(10) International Publication Number
WO 02/092152 A1

- (51) International Patent Classification⁷: **A61M 5/14**
- (21) International Application Number: PCT/US02/14659
- (22) International Filing Date: 9 May 2002 (09.05.2002)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
09/854,711 14 May 2001 (14.05.2001) US
09/971,179 4 October 2001 (04.10.2001) US
- (71) Applicant and
(72) Inventor: **KRAUSHAAR, Timothy, Y.** [US/US]; 115 4th Street, Seal Beach, CA 90740 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ (utility model), DE, DK, DM, DZ, EC, EE (utility model), ES, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK (utility model), SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- (74) Agents: **KLEIN, Howard, J.** et al.; Klein, O'Neill & Singh, Suite 510, 2 Park Plaza, Irvine, CA 92614 (US).
- Published: — with international search report

[Continued on next page]

(54) Title: IV ADMINISTRATION SET IDENTIFICATION SYSTEM



(57) Abstract: A system is used for identifying IV administration set components, wherein the IV set (10) includes an IV solution container (12), a drip chamber (14) having a hollow spike (16) for introduction into the container, and an IV line for delivering the IV solution to a patient. The system includes a first identification element (38) that is removably attached to the drip chamber for subsequent attachment to the container; a second identification element (40) permanently affixed to the drip chamber; and a third identification element (42) that is either permanently or removably attached to a Y-site or port in the IV line. The first, second, and third identification elements bear matching identification symbols.



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- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

IV ADMINISTRATION SET IDENTIFICATION SYSTEM

BACKGROUND OF THE INVENTION

The present invention relates to a system for uniquely identifying each one of two or more intravenous (IV) lines that may be simultaneously employed to deliver drugs intravenously to one or more patients respectively from two or more containers (such as IV bags or bottles).

There are medical situations, such as emergency rooms, trauma centers, and wards, in which two or more patients are simultaneously receiving IV drugs. Also, a single hospital patient often requires the administration of multiple IV drugs delivered separately, but simultaneously, through two or more separate IV sets, at widely different dosage rates. In such situations, it is necessary to assure that each container of drug solution is properly matched to the correct IV line and from there to the correct patient. Confusion in matching these elements must be avoided to assure that each drug is administered in the proper dosage to the proper patient, lest a patient be injured through the administration of the wrong drug or an improper dose of the correct drug. Additionally, there have been numerous instances of contraindicated medications being introduced into an IV line at a "Y- site" or an in-line port, with possible endangerment of the patient. To date, efforts to avoid such confusion have largely been *ad hoc*. For example, medical personnel may attach numbered pieces of adhesive tape to IV containers and to IV lines to match them up properly. Still, a more reliable mechanism has been sought to achieve these ends.

SUMMARY OF THE INVENTION

Broadly, the present invention is a system for identifying IV administration set components, wherein the IV set includes an IV solution container, a drip chamber having a hollow spike for introduction into the container, and an IV line for delivering the IV solution to a patient,

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1 wherein the system comprises a first identification element that is
2 removably attached to the drip chamber for subsequent attachment to the
3 container; a second identification element permanently affixed to the drip
4 chamber; and a third identification element attached to a Y-site or port in
5 the IV line.

6 In a specific preferred embodiment, the first identification element is
7 a strip or patch that is adhesively attached to the drip chamber in a manner
8 that will allow it to be removed therefrom for subsequent attachment to the
9 IV solution container. The second identification element is a marker,
10 preferably a strip or a patch, that is permanently affixed to the drip
11 chamber. The third identification element is attached to a Y-site or port
12 that is part of the IV line. The third identification element may be an
13 integral part of the Y-site or port, or it may be removably attached to it.
14 The first, second, and third identification elements bear matching
15 identification symbols. In the context of this invention, the term "symbol"
16 is deemed to encompass one or more letters, numbers, geometric shapes,
17 abstract shapes, colors, and any combination of these elements. The term
18 "symbol" may also include a color alone.

19 Viewed another way, the system of the invention comprises a
20 matched set of plural identification elements bearing matching
21 identification symbols, wherein a first one of the set is attachable to the IV
22 container; a second one of the set is attached to the drip chamber; and a
23 third one of the set is attached to the IV line remote from the first and
24 second identification elements in the set. In practice, the system will
25 advantageously include two or more such matched sets of identification
26 elements, each set bearing a unique identification symbol. In the context
27 of this invention, however, the term "system" is meant to encompass one
28 or more such matched sets of identification elements.

29

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1 BRIEF DESCRIPTION OF THE DRAWINGS

2 Figure 1 is an elevation view of an IV administration set
3 identification system in accordance with a preferred embodiment of the
4 present invention, showing the system in use on a typical IV
5 administration set;

6 Figure 2 is an elevational view of the first identification element of
7 the IV set identification system used on the IV administration set of
8 Figure 1;

9 Figure 3 is an elevational view of the second identification element
10 of the IV set identification system shown in Figure 1;

11 Figure 4 is an elevational view of the third identification element of
12 the IV set identification system shown in Figure 1;

13 Figures 5, 6, 7, and 8 are elevational views of identification elements
14 showing alternative types of identification symbols;

15 Figure 9 is a side elevational view of a modified form of the third
16 identification element that is removably attached to a Y-site or port;

17 Figure 10 is a front elevational view of the modified third
18 identification element and the Y-site or port to which it is removably
19 attached, taken along line 10 - 10 of Figure 9; and Figure 11 is a bottom
20 plan view of the modified third identification element and the Y-site or
21 port to which it is removably attached, taken along line 11 - 11 of Figure
22 10.

23

24 DETAILED DESCRIPTION OF THE INVENTION

25 Referring first to Figure 1, a typical IV administration set 10 is
26 shown, comprising a flexible plastic bag 12 serving as a container or
27 reservoir for an IV drug solution (not shown). The set 10 also includes a
28 drip chamber 14 having a hollow needle or spike 16 adapted to puncture
29 the bag 12. The drip chamber 14 has an outlet 18 that communicates with

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1 a first segment 20 of a flexible IV line. The first IV line segment 20 has an
2 outlet end that communicates with a first inlet branch 22 of a Y-shaped
3 port or "Y-site" 24. The Y-site 24 is modified in accordance with the
4 present invention, as will be described below. The Y-site 24 may
5 advantageously have a second inlet branch 26 sealed by a puncturable
6 septum 28. The septum 28 may be punctured by the needle of a syringe
7 (not shown), or opened by a Luer connector or other device (not shown),
8 for the administration of a supplemental drug into the IV line through the
9 second inlet branch 26, as is well known in the art. The Y-site 24 has an
10 outlet branch 30 that communicates with a second segment 32 of the
11 flexible IV line, which terminates in an IV needle (not shown) that is
12 adapted for insertion into a vein of a patient (not shown). Preferably, the
13 outlet branch 30 is aligned axially with the second inlet branch 26, so as to
14 form therewith a continuous tubular body.

15 The identification system of the present invention is shown in
16 Figures 1, 2, 3, and 4. The system comprises a first identification element,
17 in the form of a first adhesive patch or strip 38 (Figure 2); a second
18 identification element, preferably in the form of a second adhesive strip or
19 patch 40 (Figure 3); and third identification element, in the form of a
20 flattened extension 42 that extends outwardly from the tubular body that
21 comprises the second inlet branch 26 and the outlet branch 30 of the Y-site
22 24, and that is advantageously formed integrally therewith (Figure 4).

23 The first adhesive strip or patch 38 (Figure 2) includes a pull tab 48
24 at one end and an adhesive backing 50 on its reverse side, but not on the
25 back of the pull tab 48. The first adhesive strip or patch 38 is initially
26 adhesively attached to the drip chamber 14 (as shown in Figure 2 and in
27 solid outline in Figure 1). When the identification system of the present
28 invention is used, however, the first adhesive strip or patch 38 is removed
29 from the drip chamber 14 by means of the pull tab 48, and it is then

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1 adhesively applied to the exterior of the IV container 12, as shown in
2 broken outline in Figure 1.

3 The second adhesive strip or patch 40 also has an adhesive backing
4 44 (Figure 3) that allows it to be fixed to the drip chamber 14 (as shown in
5 Figure 1). The adhesive backing 44 is advantageously such as to fix the
6 second strip or patch 40 permanently to the drip chamber 14 as a
7 permanent marker. Alternatively, the second identification element may
8 simply be an identification symbol permanently marked on the drip
9 chamber.

10 The first adhesive strip or patch 38, the second adhesive strip or
11 patch 40, and the coupler extension 42 are each marked with a matching
12 identification symbol 46. As shown in Figures 1, 2, 3, and 4, the symbol
13 46 may be a numeral. Preferably, color may be used as part of the
14 identification symbols 46, whereby the symbols 46 have a matching color
15 as well as a matching number. Still more preferably, the Y-site 24 may be
16 made in the same color as the symbols 46.

17 In use, the identification system of the present invention will usually
18 comprise two or more sets of identification elements, each set comprising a
19 first strip or patch 38, a second strip or patch 40, and a Y-site 24 with an
20 extension 42 bearing the same identification symbol 46, unique to that set.

21 Figures 5, 6, and 7 show alternative forms of the identification
22 system, using different types of identification symbols. In Figure 5 the
23 symbol 46' is a letter, preferably in combination with a matching color. In
24 Figure 6 the symbol 46" is a color alone, the matching color being the
25 predominant (if not sole) color of both the tab 42 and the strip 40. In
26 Figure 7 the symbol 46'" is a colored geometric shape. Still other types of
27 symbols may be Roman numerals, abstract shapes and designs, and letters
28 of non-Latin alphabets.

29 Figure 8 illustrates an alternative form of the third identification

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1 element. In this form, the coupler or Y-site 52 is structurally an ordinary
2 device of this type, lacking the extension 42 described above. The Y-site
3 52 is marked with an identification symbol 54 by means of a band 56
4 attached around the inlet branch of the coupler 52, the band 56 bearing the
5 symbol 54. The band 56 is preferably applied as a segment of shrink
6 tubing, but it may also be in the form of an adhesive strip.

7 In use, the practitioner is provided with a drip chamber 14 to which
8 the first identification element 38 is removably attached and the second
9 identification element 40 is permanently fixed, and an IV line 20 having a
10 Y-site or port 24 that includes the third identification element 42. When
11 an IV solution container 12 is selected, the drip chamber 14 is connected to
12 the IV solution container 12 (by means of the hollow spike 16). The first
13 identification element 38 is then removed from the drip chamber 14 and
14 attached to the IV solution container 12. In this manner, a high degree of
15 certainty is provided that the IV solution container is matched to the
16 proper IV line.

17 Figures 9, 10, and 11 illustrate another modified form of the third
18 identification element. In this form, the third identification element is in
19 the form of an attachment 60 that is removably attachable to a standard Y-
20 site 62 having a first inlet branch 63a and a second inlet branch 63b. The
21 attachment 60 comprises a sleeve 64 with an axial slit 66 and an integral
22 lateral extension 68 that is marked with an identification symbol 70. The
23 integral extension 68 is preferably located diametrically opposite the axial
24 slit 66, and it is oriented substantially parallel to the slit 66. The sleeve 64
25 is made of a resilient, flexible, plastic material, and it is shaped and
26 dimensioned to fit over and to conform to the exterior surface of the Y-site
27 62. The sleeve 64 can thus be slightly spread apart along the axial slit 66
28 to allow the second IV line 32 downstream from the Y-site 62 to be passed
29 through the slit 66, and then the attachment 60 is pushed upwardly from

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1 the lower (downstream) end of the Y-site 62 until the Y-site 62 is received
2 in the sleeve 64. The sleeve 64 is widened at its upper (upstream) end to
3 accommodate the first inlet branch 63a of the Y-site 62. Likewise, the slit
4 66 is widened at its upper (upstream) end to accommodate the second inlet
5 branch 63b of the Y-site 62. The attachment 60 may be removed by just
6 reversing the aforementioned installation process. Alternatively, the
7 attachment 60 can be installed snapping the sleeve 64 directly onto the Y-
8 site 62 by spreading the sleeve 64 apart along the slit 66. Likewise, the
9 sleeve 64 can be spread apart along the slit 66 for removal from the port or
10 Y-site 62.

11 The method of using the modified form of the invention is the same
12 as described above, except that the practitioner is provided with an IV line
13 having a standard Y-site or port 62 and an appropriate snap-on member 60
14 for attachment to the Y-site 62. When an IV solution container 12 is
15 selected, the drip chamber 14 is connected to it, and the first identification
16 element is removed from the drip chamber and applied to the solution
17 container. The third identification element (attachment 60) is then
18 attached to the Y-site 62 (as described above), the attachment 60 having an
19 identification symbol 70 that matches the identification symbol on the first
20 and second identification element.

21 While a preferred embodiment of the invention has been described
22 herein, it will be appreciated that a number of variations and modifications
23 will suggest themselves to those skilled in the pertinent arts. These
24 variations and modifications are considered within the spirit and scope of
25 the invention, as defined in the claims that follow.

1 WHAT IS CLAIMED IS:

2
3 1. A system for identifying IV administration set components,
4 wherein the IV administration set includes an IV solution container, a drip
5 chamber, and an IV line having a port, the system comprising:

6 a first identification element that is removably attached to the drip
7 chamber for subsequent attachment to the container;

8 a second identification element fixed to the drip chamber; and

9 a third identification element attached to the port.

10
11 2. The system of Claim 1, wherein the first identification element
12 includes a patch that is adhesively attached to the drip chamber in a
13 manner that allows it to be removed therefrom for subsequent attachment
14 to the container.

15
16 3. The system of Claim 1, wherein the second identification
17 element includes a marker that is permanently fixed to the drip chamber.

18
19 4. The system of Claim 1, wherein the third identification element
20 is an integral part of the port.

21
22 5. The system of Claim 1, wherein the first, second, and third
23 identification elements bear matching identification symbols.

24
25 6. The system of Claim 5, wherein the identification symbols are
26 selected from the group consisting of Arabic numerals, Roman numerals,
27 letters, geometric shapes, abstract shapes, and colors.

28
29 7. The system of Claim 1, wherein the third identification element

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1 includes a band attached to the port.

2

3 8. The system of Claim 7, wherein the band is applied to the port as
4 a segment of shrink tubing.

5

6 9. The system of Claim 7, wherein the band is adhesively attached
7 to the port.

8

9 10. A method of identifying the components in an IV
10 administration set that includes an IV solution container, a drip chamber,
11 and an IV line having a port, the method comprising the steps of:

12 (A) providing a drip chamber having a first identification element
13 removably attached thereto and a second identification element
14 permanently fixed thereto;

15 (B) providing a port having a third identification element as a part
16 thereof;

17 (C) removing the first identification element from the drip chamber;
18 and

19 (D) attaching the first identification element to the IV solution
20 container.

21

22 11. The method of Claim 10, wherein the first, second, and third
23 identification elements bear matching identification symbols.

24

25 12. The system of Claim 11, wherein the identification symbols are
26 selected from the group consisting of Arabic numerals, Roman numerals,
27 letters, geometric shapes, abstract shapes, and colors.

28

29 13. The method of Claim 10, wherein the drip chamber is

1 connected to the IV solution container before the step of removing the first
2 identification element from the drip chamber is performed.

3
4 14. A system for identifying IV administration set components,
5 wherein the IV administration set includes an IV solution container, a drip
6 chamber, and an IV line having a port, the system comprising:

7 a first identification element that is removably attached to the drip
8 chamber with an adhesive that allows it to be subsequently attached to the
9 container;

10 a second identification element permanently fixed to the drip
11 chamber; and

12 a third identification element attached to the port;

13 wherein the first, second, and third identification elements are
14 marked with matching identification symbols.

15
16 15. The system of Claim 14, wherein the third identification element
17 is an integral part of the port.

18
19 16. The system of Claim 14, wherein the third identification
20 element includes a band attached to the port.

21
22 17. The system of Claim 14, wherein the band is applied to the port
23 as a segment of shrink tubing.

24
25 18. The system of claim 14, wherein the band is adhesively attached
26 to the port.

27
28 19. The system of Claim 14, wherein the identification symbols are
29 selected from the group consisting of Arabic numerals, Roman numerals,

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1 letters, geometric shapes, abstract shapes, and colors.

2
3 20. A system for identifying IV administration set components,
4 wherein the IV administration set includes an IV solution container, a drip
5 chamber, and an IV line having a port, the system comprising:

6 a first identification element that is removably attached to the drip
7 chamber for subsequent attachment to the container;

8 a second identification element fixed to the drip chamber; and

9 a third identification element that is removably attachable to the
10 port.

11
12 21. The system of Claim 20, wherein the first identification element
13 includes a patch that is adhesively attached to the drip chamber in a
14 manner that allows it to be removed therefrom for subsequent attachment
15 to the container.

16
17 22. The system of Claim 20, wherein the second identification
18 element includes a marker that is permanently fixed to the drip chamber.

19
20 23. The system of Claim 20, wherein the third identification
21 element comprises:

22 a tubular body of flexible resilient material, configured to fit over
23 and to conform to the exterior surface of the port, the tubular body having
24 an axial slit; and

25 an integral extension extending from the tubular body at a location
26 diametrically opposite the slit.

27
28 24. The system of Claim 20, wherein the first, second, and third
29 identification elements bear matching identification symbols.

1 25. The system of Claim 24, wherein the identification symbols are
2 selected from the group consisting of Arabic numerals, Roman numerals,
3 letters, geometric shapes, abstract shapes, and colors.

4
5 26. A method of identifying the components in an IV
6 administration set that includes an IV solution container, a drip chamber,
7 and an IV line having a port, the method comprising the steps of:

8 (A) providing a drip chamber having a first identification element
9 removably attached thereto and a second identification element
10 permanently fixed thereto;

11 (B) providing a third identification element that is attachable to the
12 port;

13 (C) removing the first identification element from the drip chamber;

14 (D) attaching the first identification element to the IV solution
15 container; and

16 (E) attaching the third identification element to the port.

17
18 27. The method of Claim 26, wherein the first, second, and third
19 identification elements bear matching identification symbols.

20
21 28. The system of Claim 27, wherein the identification symbols are
22 selected from the group consisting of Arabic numerals, Roman numerals,
23 letters, geometric shapes, abstract shapes, and colors.

24
25 29. The method of Claim 26, wherein the drip chamber is
26 connected to the IV solution container before the step of removing the first
27 identification element from the drip chamber is performed.

28
29 30. A system for identifying IV administration set components,

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1 wherein the IV administration set includes an IV solution container, a drip
2 chamber, and an IV line having a port, the system comprising:

3 a first identification element that is removably attached to the drip
4 chamber with an adhesive that allows it to be subsequently attached to the
5 container;

6 a second identification element permanently fixed to the drip
7 chamber; and

8 a third identification element that is removably attachable to the
9 port;

10 wherein the first, second, and third identification elements are
11 marked with matching identification symbols.

12

13 31. The system of Claim 30, wherein the identification symbols are
14 selected from the group consisting of Arabic numerals, Roman numerals,
15 letters, geometric shapes, abstract shapes, and colors.

16

17 32. The system of Claim 30, wherein the third identification
18 element comprises:

19 a tubular body of flexible resilient material, configured to fit over
20 and to conform to the exterior surface of the port, the tubular body having
21 an axial slit; and

22 an integral extension extending from the tubular body at a location
23 diametrically opposite the slit.

24

25 33. The system of Claim 32, wherein the extension is marked with
26 an identification symbol.

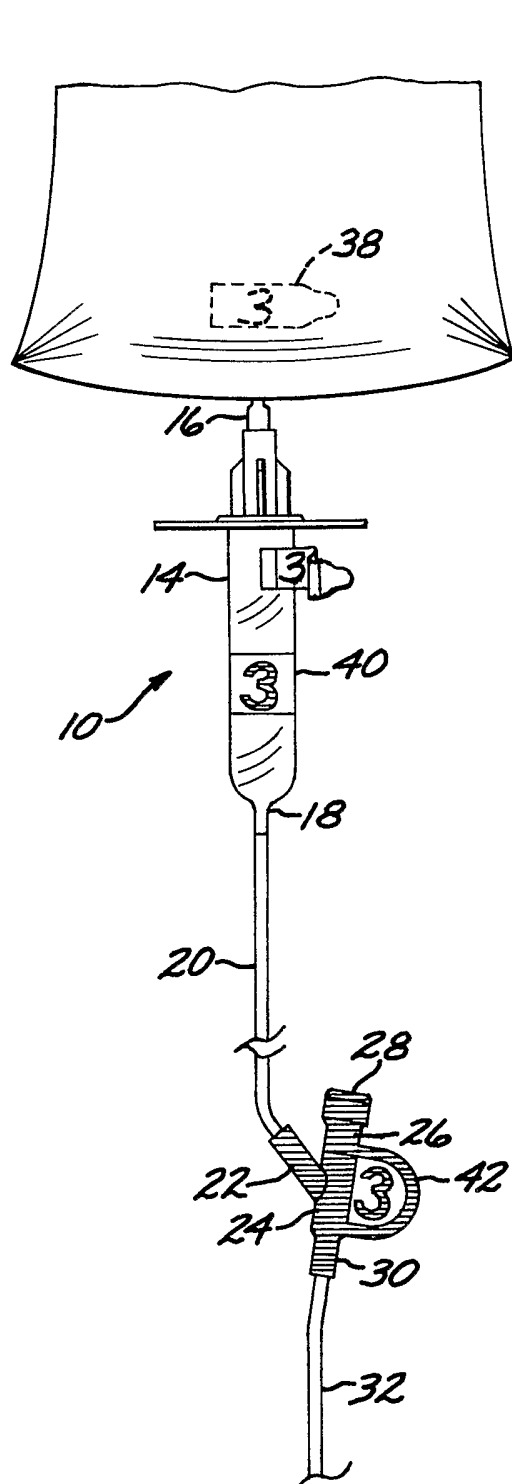


FIG. 1

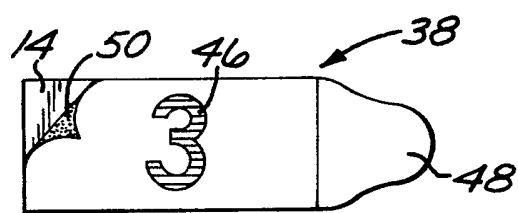


FIG. 2

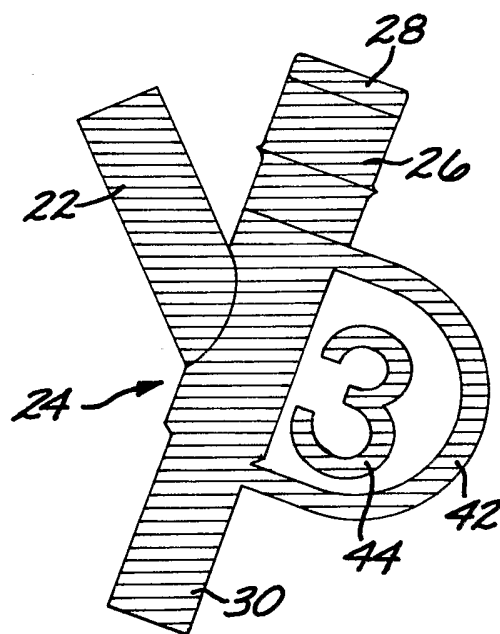


FIG. 4

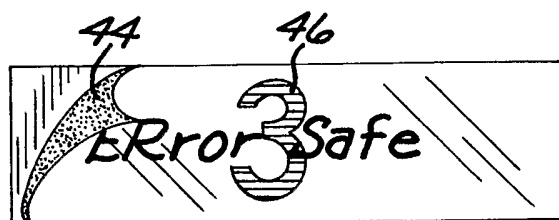
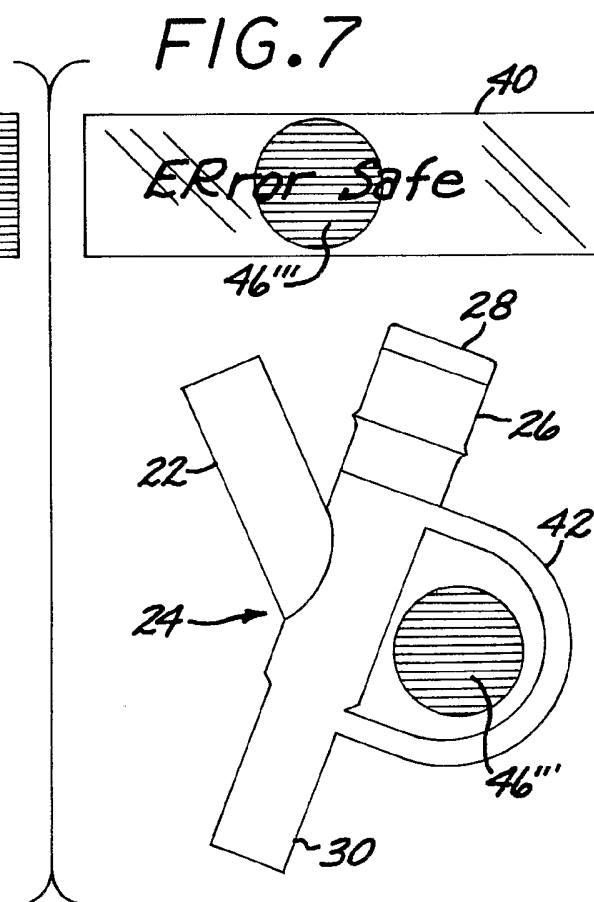
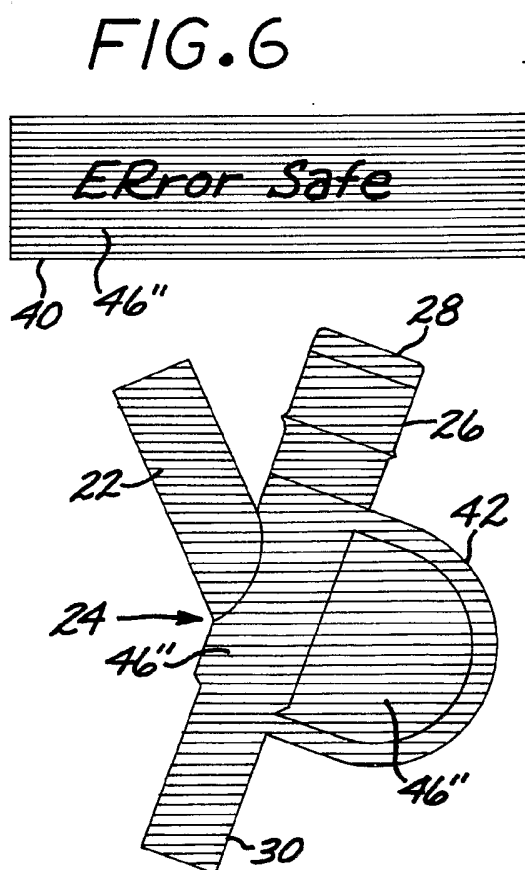
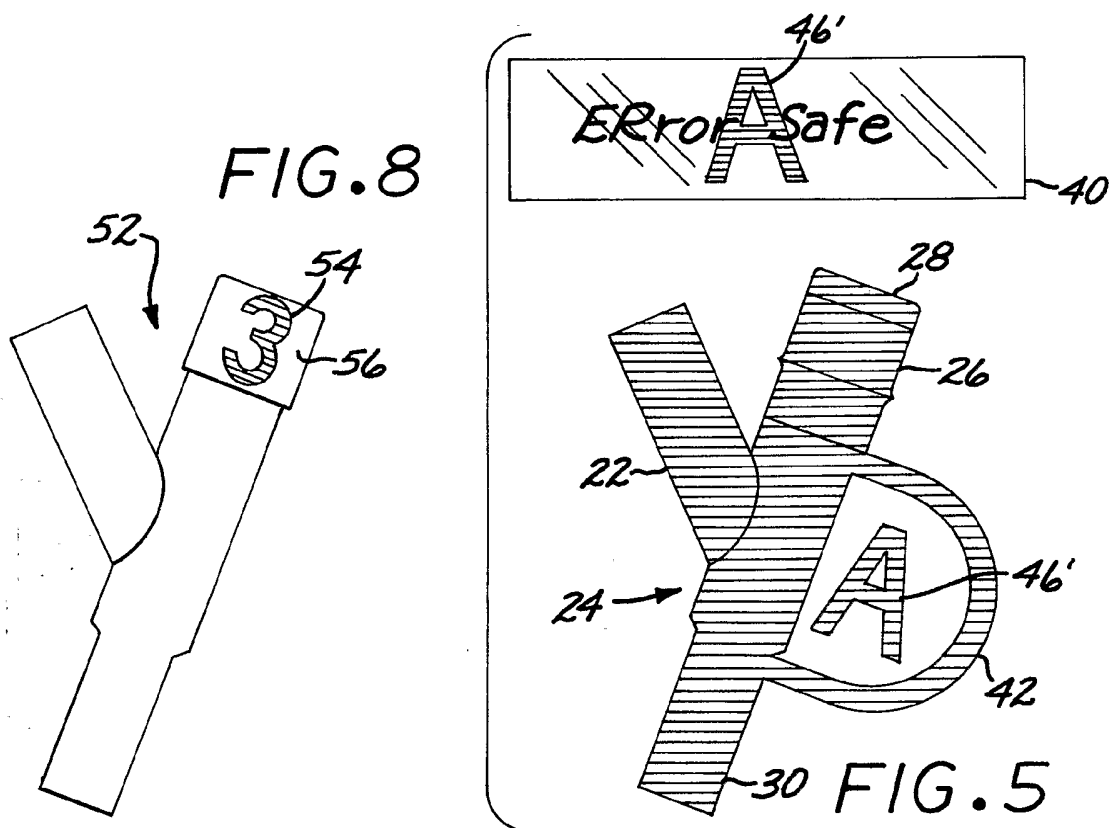


FIG. 3



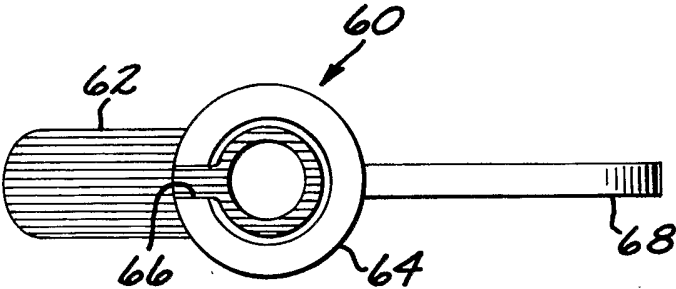
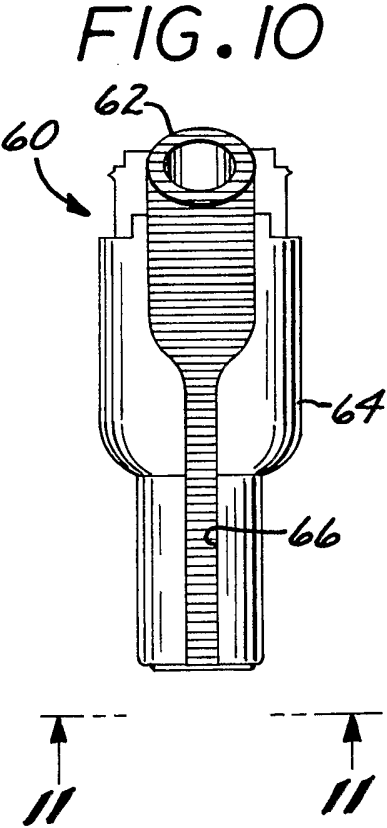
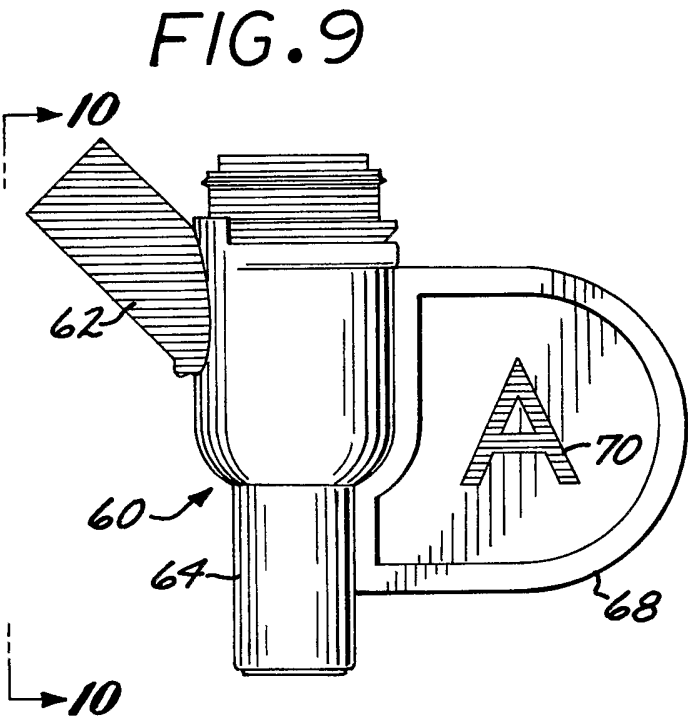


FIG. 11

INTERNATIONAL SEARCH REPORT

Int onal Application No

PCT/US 02/14659

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M5/14

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)

IPC 7 A61M A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	DE 297 20 382 U (PIEROTH WALTER) 27 August 1998 (1998-08-27) the whole document ---	1-33
X	US 5 224 932 A (LAPPAS DOLORES M) 6 July 1993 (1993-07-06) the whole document ---	1-33
A	US 4 795 429 A (FELDSTEIN MARVIN A) 3 January 1989 (1989-01-03) abstract column 7, line 13 -column 10, line 60 --- -/--	1-33



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

° Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
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Date of the actual completion of the international search

27 September 2002

Date of mailing of the international search report

07/10/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Jameson, P

INTERNATIONAL SEARCH REPORT

Int. Patent Application No.
PCT/US 02/14659

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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information on patent family members

International Application No

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US 4795429	A	03-01-1989	NONE	
US 4999885	A	19-03-1991	NONE	
US 5657874	A	19-08-1997	US 5657873 A US 5375701 A AT 133912 T CA 2054670 A1 DE 69117009 D1 DE 69117009 T2 EP 0488531 A2 ES 2084784 T3 JP 4352657 A	19-08-1997 27-12-1994 15-02-1996 07-05-1992 21-03-1996 25-07-1996 03-06-1992 16-05-1996 07-12-1992