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(71) Applicant(s)  
**Alcon, Inc.**

(72) Inventor(s)  
**Domash, David M.; Foster, James J.**

(74) Agent / Attorney  
**Phillips Ormonde Fitzpatrick, 367 Collins Street, Melbourne, VIC, 3000**

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(71) Applicant (for all designated States except US): **ALCON, INC.** [CH/CH]; P.O. Box 62, Bosch 69, CH-6331 Hunenberg (CH).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **DOMASH, David, M.** [US/US]; 15 Springwood, Irvine, California 92604 (US). **FOSTER, James, J.** [US/US]; 515 North Linwood, Santa Ana, California 92701 (US).

(74) Agents: **LEE, W. David** et al.; Alcon Research, LTD., IP Legal, Mail Code TB4-8, 6201 South Freeway, Fort Worth, Texas 76134 (US).

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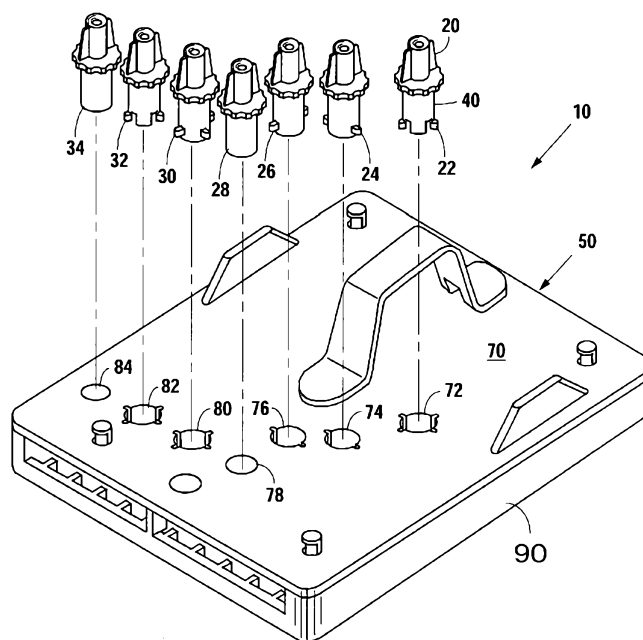
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(54) Title: CONNECTOR TO CASSETTE INTERFACE SYSTEM



(57) Abstract: The disclosed connector to cassette interface system includes a set of individual keyed connectors having a shroud on the lower portion. The perimeter of each shroud includes an array of tabs or protrusions keyed to one of a corresponding array of skirted portals in the cassette cover. The tabs or protrusions on the shroud portion of each individual keyed connector may further serve to prevent rotation of each connector beyond about 60°.

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**CONNECTOR TO CASSETTE INTERFACE SYSTEM****FIELD**

The present invention pertains to the connection of sources of fluid to a piece of medical/surgical equipment; more particularly, the present invention pertains to a system  
5 for mounting connectors to a cassette assembly used with a piece of medical/surgical equipment.

**BACKGROUND**

Many pieces of medical/surgical equipment are built to manage the flow of a set of different fluids associated with the performance of certain medical/surgical procedures.  
10 Such fluids may include air, liquid irrigation fluids, liquid antibiotics, blood, or in the case of eye surgery, tissue that has been removed and aspirated from the eye via a probe or handpiece. Typically, the conduit for such fluids in a piece of medical/surgical equipment is a section of silicone tubing. Those setting up a piece of medical/surgical equipment for a particular medical/surgical procedure connect individual sections of  
15 silicone tubing, one to another, to assure that the needed fluids are placed where they need to be at the proper time during the medical/surgical procedure.

Connection of silicone tubing sections, one to another, is accomplished using a variety of different types of fittings. One of the more popular types of fittings used with silicone tubing sections in medical/surgical equipment is a luer fitting. In a luer fitting a  
20 tapered male luer fitting engages a similarly tapered female luer fitting. The male and female luer fittings may be held together by a set of internally and externally threaded connectors which surround the male and female luer fittings once they have been mated together. When the male and female tapered luer fittings have been mated together and the threaded connectors have been threadably engaged together around the male and

female luer fittings, a secure connection is made between two sections of silicone tubing permitting the leak-free flow of a fluid therethrough.

Because different sets of fluids are associated with each procedure that can be performed with a piece of medical/surgical equipment, some pieces of medical/surgical  
5 equipment use replaceable manifolds or cassettes to facilitate the grouping of the necessary tubing connections. In this manner, the appropriate set of fluids needed to perform a selected medical/surgical procedure from the set of available medical/surgical procedures enabled by a piece of medical/surgical equipment is provided.

To distinguish between connections when multiple tubing connections are placed  
10 close to one another, engineers and designers of medical/surgical equipment typically use different sizes of luer fittings. However, engineers and designers quickly run out of luer fitting size options when multiple types of fluids are used.

The existing problem of properly mating a plurality of luer fittings together with the limited number of luer fitting connection sizes available has been solved in the prior  
15 art by the use of silicone tubing sleeves which are used during the pre-connection process. In one particular prior art solution, pre-attached silicone tubing sleeves have been used to attach bottle spike tubing to a manifold or cassette used with a piece of medical/surgical equipment while maintaining the male luer geometry. Pre-attached prior art silicone tubing sleeves are used primarily to provide stress relief for the connections to silicone  
20 tubing sections and to enable pre-attachment of prior art silicone tubing sections to the manifolds or cassettes used in medical/surgical equipment.

It has been found that prior art pre-attached silicone tubing sleeves are costly and difficult to incorporate into the automated manufacture of medical/surgical equipment. In addition, prior art silicone tubing sleeves are difficult to place over the recessed fittings  
25 located in the manifold or cassette assembly. Prior art silicone tubing sleeves are also not as simple to remove and reapply as typical luer fittings. Further, pre-attached prior art

silicone tubing sleeves cannot be aseptically connected to the manifold or cassette assembly.

There are additional drawbacks to the pre-attached prior art silicone tubing sleeves. Some pre-attached prior art silicone tubing sleeves cannot endure the rigors of shipping. Pre-attached prior art silicone tubing sleeves do not allow for physical lockout of a connector when an improper connection with a manifold or cassette assembly is attempted.

It is well known that improper or cross connection of fluids to a piece of medical/surgical equipment presents a patient safety issue and can result in the creation of a dangerous condition. Accordingly, a need remains in the art for a connector to cassette assembly interface system that can be used to facilitate the set up of a piece of medical/surgical equipment for a particular medical/surgical procedure. The connector to cassette assembly interface system should provide secure connectors for luer fittings, provide a lockout if an improper connection is attempted, and protect the male and female portions of the luer fitting from contamination.

A reference herein to a patent document or other matter which is given as prior art is not to be taken as an admission or a suggestion that that document or matter was known or that the information it contains was part of the common general knowledge as at the priority date of any of the claims.

## SUMMARY

According to a first aspect, the present invention provides a cassette for engagement with a connector having a lower portion which includes a luer fitting surrounded by a shroud, said shroud having a unique diameter and a unique array of tabs extending therefrom, said cassette comprising: a cassette cover said cassette cover having a plurality of portals formed thereon, each of said portals provided with a skirt portion having a unique size and a unique

array of openings formed therein; and a cassette body having a plurality of tubular openings formed therein, said tubular openings being constructed and arranged to align with said portals when said cassette cover is placed on said cassette body;

5 BRIEF DESCRIPTION OF THE DRAWING FIGURES

A better understanding of the connector to cassette interface system of the present invention may be had by reference to the drawing figures, wherein:

Figure 1 is a perspective view of a manifold or cassette assembly together with a set of connectors;

10 Figure 2A is a perspective view of a keyed connector showing a luer fitting within the lower portion;

Figure 2B is a perspective view of the keyed connector illustrated in Figure 2A showing its upper portion;

Figure 3 is an exploded view of the manifold or cassette assembly together with the set of keyed connectors as shown in Figure 1;

5 Figure 4A is a perspective view of the top of the cover portion of the manifold or cassette assembly;

Figure 4B is a perspective view of the bottom of the cover portion of the manifold or cassette assembly;

10 Figure 4C is a perspective view of the body portion of the manifold or cassette assembly;

Figure 5 is a perspective view, in partial section, showing a set of individual connectors mounted in the manifold or cassette assembly;

Figure 6 is a perspective view of a first alternative of a shroud and skirted portal engagement; and

15 Figure 7 is a perspective view of a second alternative of a shroud and skirted portal engagement including a ratchet mechanism.

## DESCRIPTION OF THE EMBODIMENTS

It is the purpose of the disclosed invention to provide a connector to cassette interface system that has the following features:

- 20
- 1) A lock-out system for use when connecting a set of silicone tubing sections to a manifold or cassette assembly which uses an array of unique key geometries on each connector to remove the risk of cross connection between tubing sections. Specifically:
    - 25 a) A set of tabs or protrusions extending from the lower portion of each connector which provide a

unique key geometry to assure proper connection of a tubing section with a port on a manifold or cassette assembly;

5

- b) A connection portion on each connector which allows a health care professional to manually grasp each connector and easily plug the connector into the manifold or cassette assembly without contaminating the fittings portion.

10

2) Aseptic mounting of a set of keyed connectors to a manifold or cassette assembly. Specifically:

- a) A shroud having a diameter sufficient to surround the luer fitting;
- b) A shroud having a length to prevent touch contamination of the luer fitting.

15

While the disclosed connector to cassette interface system has been designed for use with an ophthalmic surgical system, those of ordinary skill in the art will understand that the disclosed connector to cassette assembly interface system may be used with a wide variety of different types of medical/surgical equipment which require connections to predetermined sets of fluids for proper performance of one or more procedures.

20

The connector to cassette interface system 10 which meets the purposes described above appears in Figure 1. The general design of each individual keyed connector 20 appears in Figures 2A and 2B. Figure 3 is an exploded view showing the mounting of individual connectors 20 into the manifold or cassette assembly 50. Once the individual connectors are inserted through the skirted portals in the cover portion 70 of the manifold or cassette assembly 50 into the body portion 90 of the manifold or cassette assembly 50,

25

they are preferably turned about 60° to a position where they contact either forward stops



92 or back stops 94 formed in the body portion 90 of the manifold or cassette assembly 50 as shown in Figures 4C and 5.

To assure proper interfitment of the keyed connectors 20 with the manifold or cassette assembly 50, the connectors 20 are designed to have a variety of different individual key designs formed around the outer surface of the bottom of the shroud 40 as shown in Figure 3. The arrangement of the array of extensions, protrusions, or tabs 22, 24, 26, 28, 30, 32, 34 on the shroud 40 create various key configurations. Shroud 40 length and shroud 40 diameter may also be used to create various shroud 40 key configurations. While substantially circular shrouds are shown in the preferred embodiment, those of ordinary skill in the art will understand that the upper portion 41 of the shroud can be circular and the lower portion 43 of the shroud 40 can be formed to have straight sides as in a triangle, rectangle, pentagon, etc.

The array of openings or portals 72, 74, 76, 78, 80, 82, 84 which form the key features on the cassette assembly 50 together with the skirts 73, 75, 77, 79, 81, 83, 85 under each opening 72, 74, 76, 78, 80, 82, 84 prevent misconnection of tubing sets to the cassette assembly 50. Although in a preferred embodiment the tubing connectors 22, 24, 26, 28, 30, 32, 34 and the openings 72, 74, 76, 78, 80, 82, 84 in the cassette cover portion 70 of the manifold or cassette assembly 50 will be color coded, a physical lock-out mechanism will not allow a tubing connector 20 to be misplaced in a hole in the cover portion 70 of the manifold or cassette assembly 50. The key interface between the shrouds 40 and the array of openings to match connectors 20 to the cover portion 70 of the manifold or cassette assembly 50 is designed so that fittings with common luer geometry are incapable of being connected to the wrong port in the cover portion of the manifold or cassette assembly 50.

By utilizing a varying number of key tabs and varying sizes of key tabs, a misconnection of common luer geometry interfaces is prevented. The geometry of the

location and size of the tabs on each shroud portion **40** of each keyed connector **20** is reflected on the specific cassette port with a unique key-hole pattern. In addition, a stop system may be located in the body portion **90** of the manifold or cassette assembly **50** to prevent a keyed connector **20** from rotating more than about  $60^\circ$  after passing into the cassette assembly **50**. The array of stops **92, 94** as shown in Figure 4C and Figure 5 are positioned in the body portion **90** of the manifold or cassette assembly **50** around the tubular openings **95** to physically contact the protrusions or tabs on each shroud **40** once the connector is rotated about  $60^\circ$  in a clockwise manner. The height of the stops **92, 94** can be established by the length of the shroud and/or the location of the tabs on each individual keyed connector **20**.

The interface between the manifold or cassette assembly **50** and the individual keyed connectors **20** also provides a method for securely pre-connecting the desired set of connectors **20** to the manifold or cassette assembly **50** for shipping. Such pre-connection of the desired set of connectors **20** further minimizes errors and reduces set-up time at a patient care facility.

The shroud portion **40** of each individual keyed connector **20** is sized to have a length which prevents touching of the recessed luer fitting **45** within each connector **20** so that each luer fitting **45** will remain aseptic. As previously indicated, the diameter and the length of each shroud **40** may also function as a physical key feature along with the tabs on each connector **20** to provide another way of making the individual keyed connectors **20** unique.

Removing each connector **20** requires about a  $60^\circ$  counter clock wise turn and axial removal. Turning of each connector is facilitated by a pair of wings **33** on the top portion of each connector **20**. A flange **35** both separates the top portion **31** of each keyed connector **20** from the shroud **40** and limits the depth of insertion of each keyed connector **20** into the cassette assembly **50**.

Each individual keyed connector including a unique array of key features provides a repeatable method of applying and removing tubing sets from a cassette assembly 50 in a sterile manner. The key features on the bottom 43 of each shroud 40 of each individual keyed connector 20 and the stops 92 and 94 surrounding the tubular openings 95 in the cassette body 90 also provide a 60° positive engagement and mitigate the risk of the disconnection of the tubing sections from the manifold or cassette assembly 50 during shipment. The key features on each individual keyed connector 20 also provide a mechanism similar to the luer lock interface without the need to unscrew core pins when the luer connectors are molded.

As may be seen in Figure 6 cassette cover portion 70 may be alternatively formed with a skirt 141 having slots 142 and openings 143 formed therein for allowing tabs 22 of connector 20 to access openings 143. Surfaces 144 and 145 of skirt 141 provide a rotation stop for tab 22. As shown in Figure 7, cassette cover portion 70 may be alternatively formed with a skirt 146 having a stepped engagement ramp 147 that acts as a ratchet mechanism for tabs 22 when connector 20 is rotated with respect to manifold or cassette assembly 50. An audible click preferably occurs when tabs 22 engage each step of ramp 147.

While the disclosed connector to cassette assembly interface system has been disclosed according to its preferred and alternate embodiments, those of ordinary skill in the art will understand that numerous other embodiments have been enabled by the foregoing disclosure. Such other embodiments shall be included within the scope and meaning of the appended claims.

Where the terms "comprise", "comprises", "comprised" or "comprising" are used in this specification (including the claims) they are to be interpreted as specifying the presence of the stated features, integers, steps or components, but not precluding the presence of one or more other feature, integer, step, component or group thereof.

The claims defining the invention are as follows:

1. A cassette 50 for engagement with a connector 20 having a lower portion which includes a luer fitting 45 surrounded by a shroud 40, said shroud having a unique diameter and a unique array of tabs (22) extending therefrom, said cassette comprising:

a cassette cover, 70, said cassette cover having a plurality of portals (72 formed thereon, each of said portals provided with provided with a skirt portion 73 having a unique size and a unique array of openings formed therein; and

a cassette body h90 having a plurality of tubular openings 95 formed therein, said tubular openings being constructed and arranged to align with said portals when said cassette cover is placed on said cassette body;

whereby each portal on said cassette cover is keyed to a single connector.

2. The cassette as defined in Claim 1 wherein said skirt portion provides for the engagement with a luer fitting of a sex opposite to the sex of the luer fitting within the shroud.

3. The cassette as defined in Claim 1 or 2 wherein said skirt portion includes a stepped ramp 147.

4. The cassette as defined in any one of the preceding claims wherein said stepped ramp is for engagement with one of said tabs.

5. The cassette as defined in any one of the preceding claims wherein said portal is color coded.

6. The cassette as defined in any one of the preceding claims wherein said cassette body further comprises an array of stops 92 formed around said tubular openings.

7. The cassette as defined in Claim 6 wherein said array of stops surrounding each tubular opening is positioned to engage the tabs.

8. The cassette as defined in Claim 7 wherein said stops have different heights constructed and arranged to engage shrouds of different lengths.

9. The cassette as defined in any one of the preceding claims wherein said skirt portions each have an opening 147 with a surface 144 that limits a rotation of said connector after said connector has been inserted into said cassette.

10. A cassette substantially as hereinbefore described with reference to the accompanying drawings.

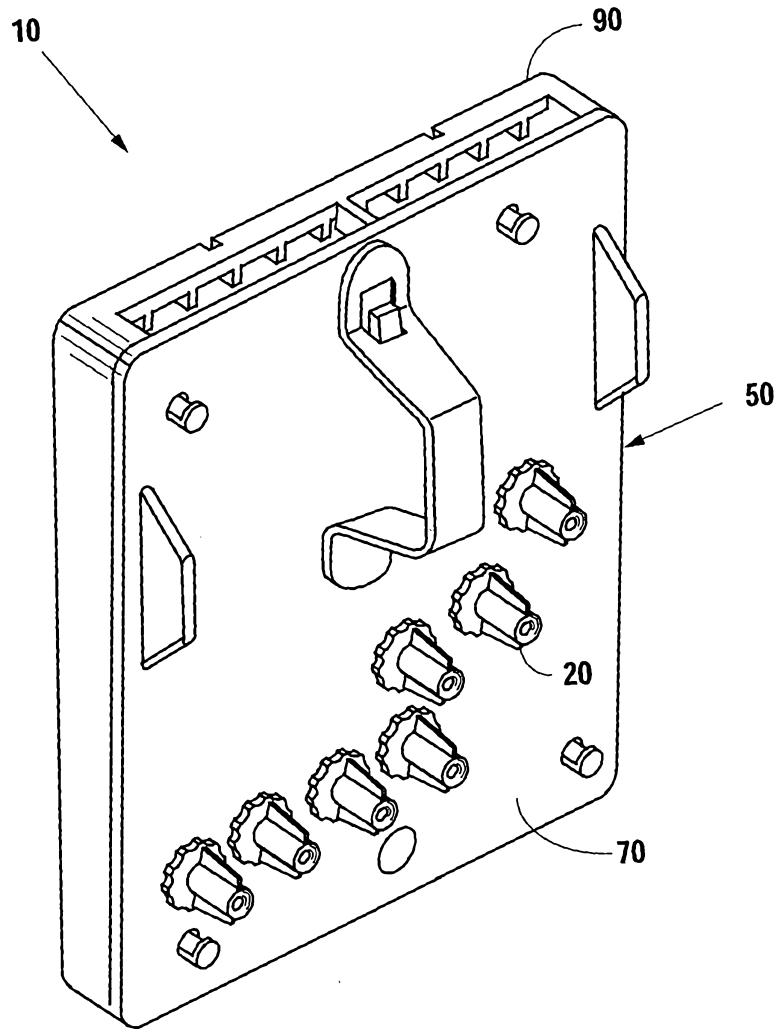


Fig. 1

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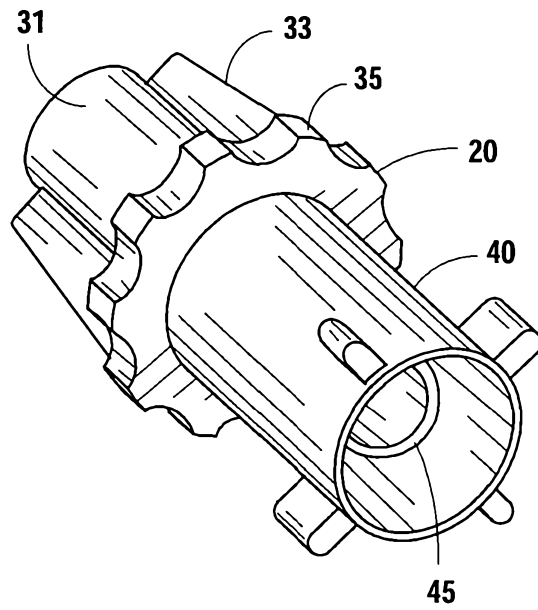


Fig. 2A

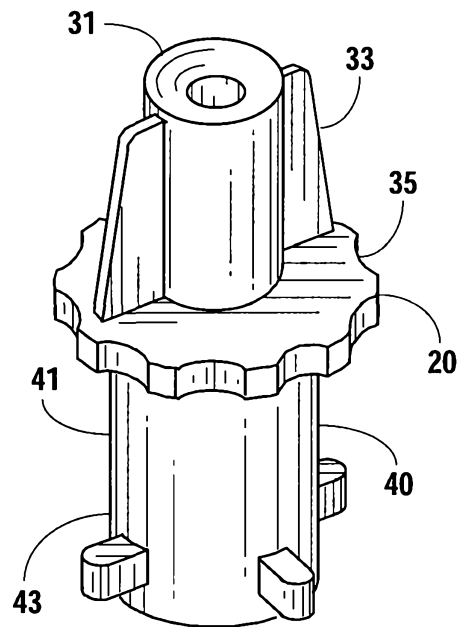


Fig. 2B

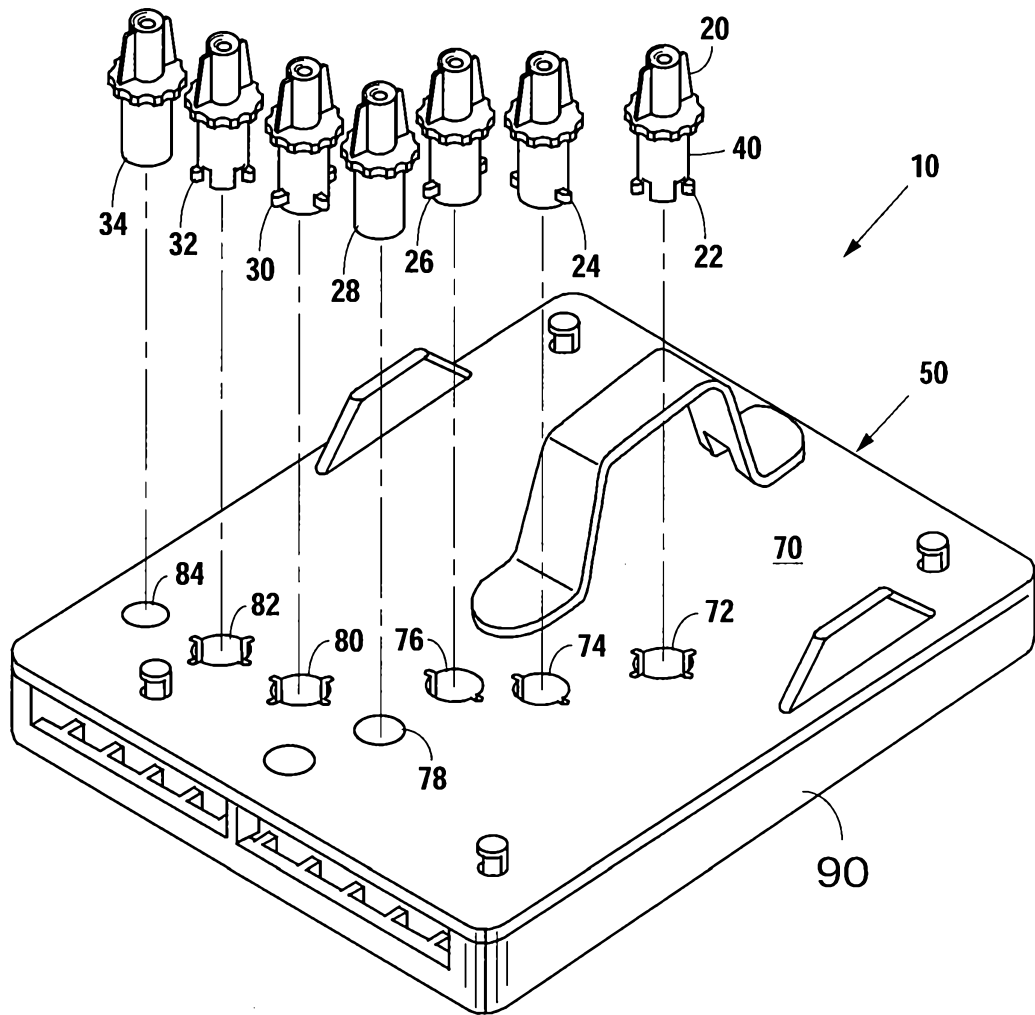
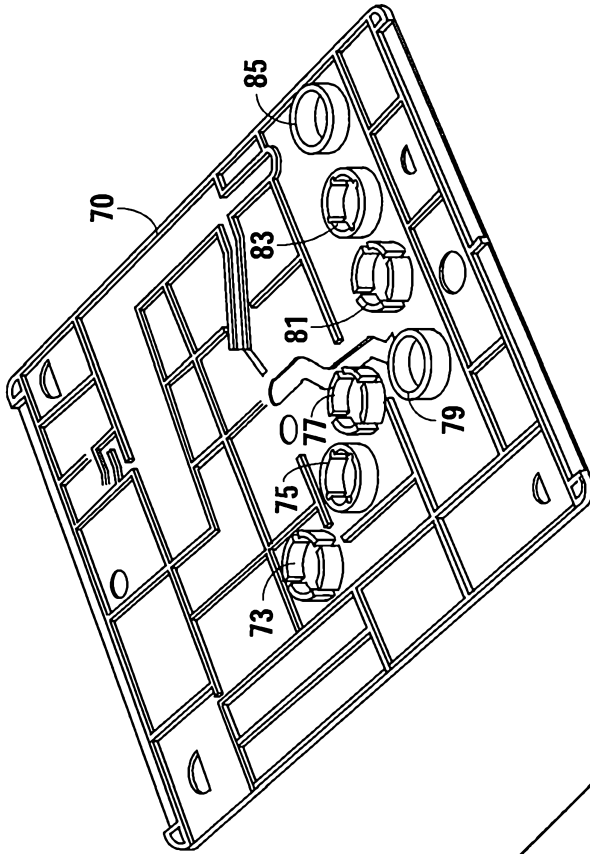
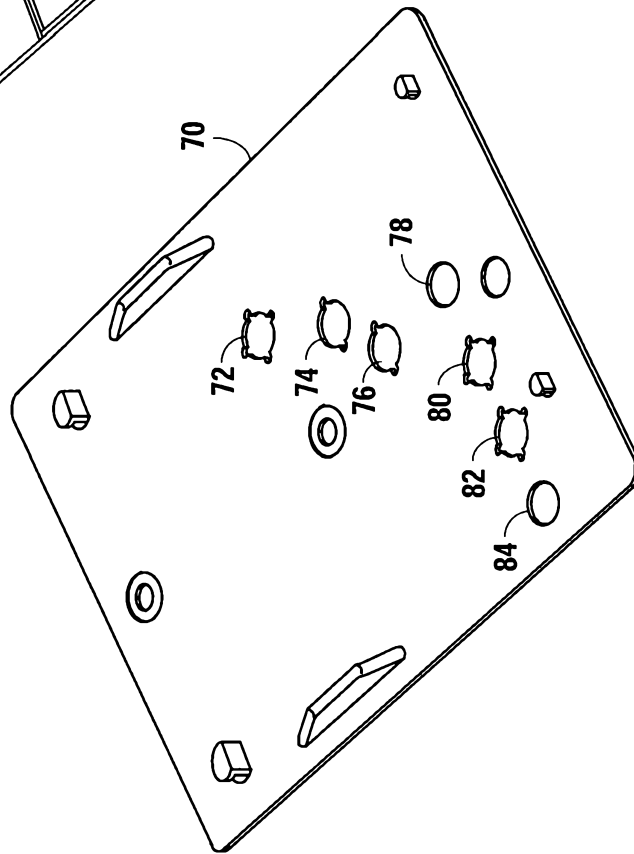


Fig. 3





*Fig. 4B*



*Fig. 4A*

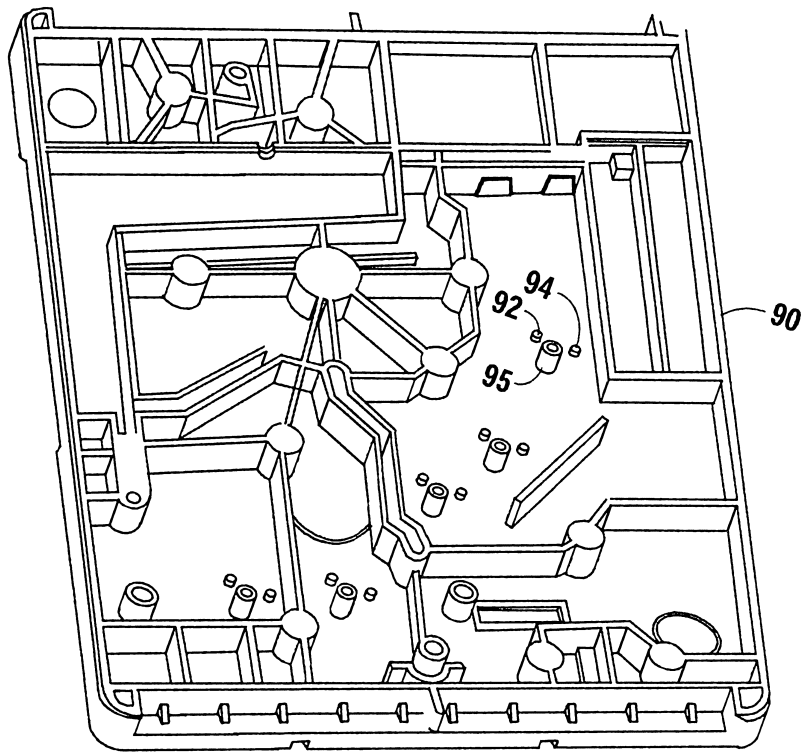
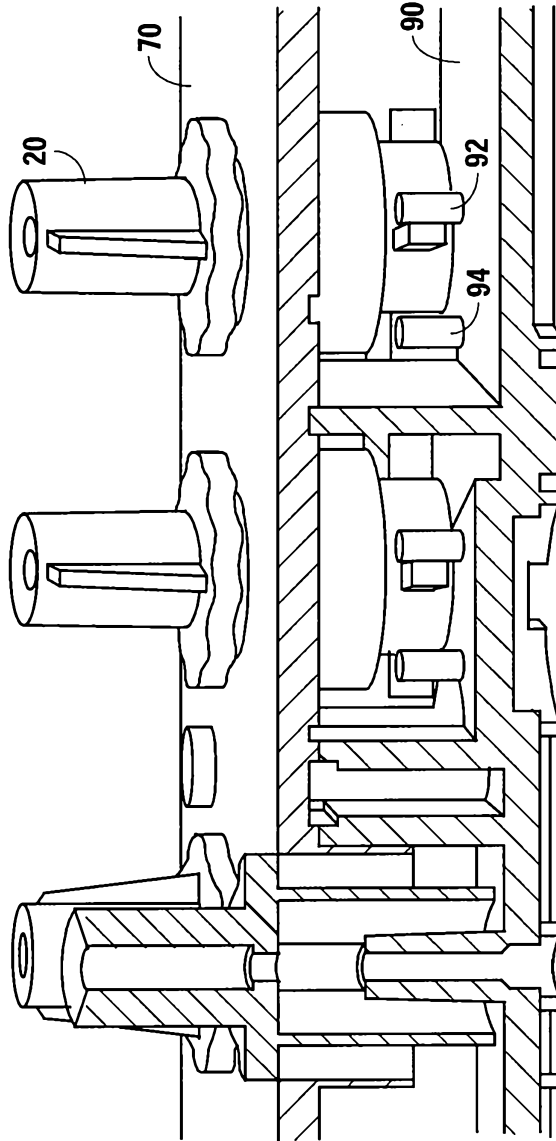


Fig. 4C



*Fig. 5*

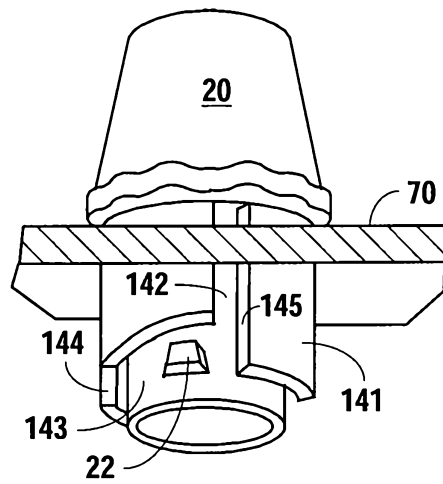


Fig. 6

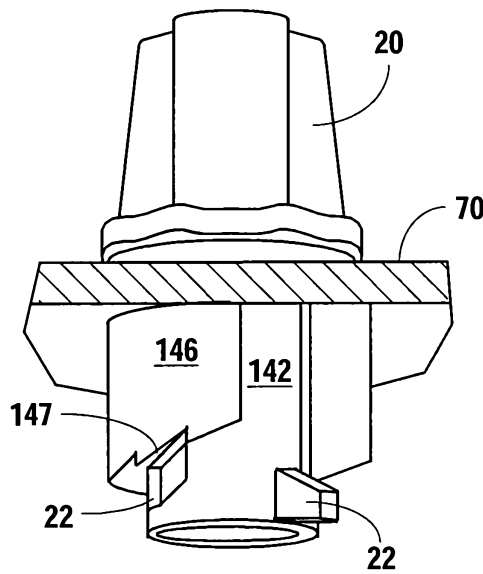


Fig. 7