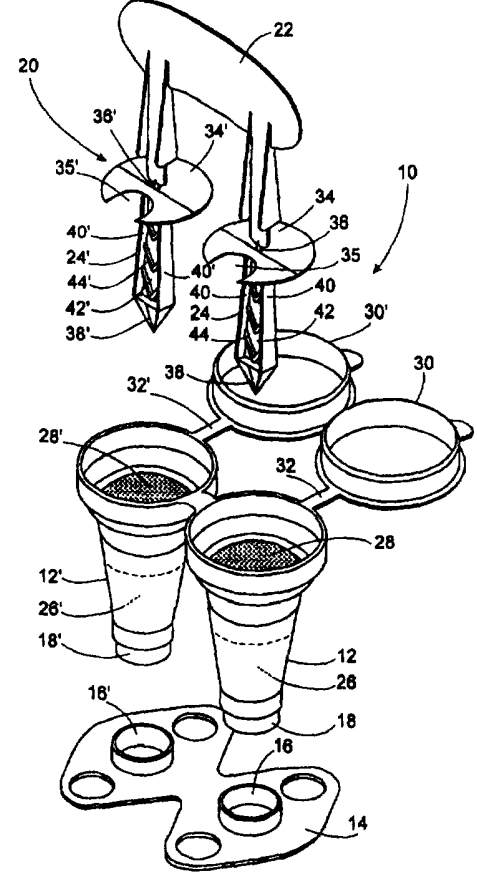




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(54) Title: COLLECTION AND TRANSPORTATION OF A PASTY MATERIAL SAMPLE		
(57) Abstract		
A system for collecting, storing and transporting of specimens of a pasty material, e.g. stool is provided. The system comprises at least one container holding a preservation medium for preserving a chemical entity or living matter to be assayed in a specimen, the container being sealed by a pierceable membrane having a closure arrangement for sealing the container after the membrane is pierced. The system further comprises a sampling device having a handle and at least one elongated specimen collecting member detachably attached thereto, the collecting member being adapted to be received within the container and having the pasty material retaining portion and a piercing tip for piercing the membrane at a lowermost end thereof remote from said handle, for piercing said film. Also provided is a stool collecting device for easy collecting of excreted stool. 		

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COLLECTION AND TRANSPORTATION OF A PASTY MATERIAL SAMPLE

FIELD OF THE INVENTION

The present invention concerns a system for the collection and transportation of a pasty material sample, for example of stool, which is to be distributed in a transport and/or suspension medium.

5

BACKGROUND OF THE INVENTION

Collection and transportation of a pasty material, such a stool, food samples, soil samples and the like for the purpose of laboratory manipulation such as detection of microorganism being bacteria or parasites, detection of cryptic blood, preparation of a biochemical profile, etc., is an essential component of modern medicine, health care and environmental management.

10

Often, when the pasty material is transported to the laboratory without a preservation medium, by the time it reaches a laboratory no viable micro-organisms can be detected, and the result of the laboratory tests are thus distorted.

15

In order to overcome this problem, various devices and systems for the collection and transportation of pasty material have been developed, in which the pasty material is distributed in a medium capable of maintaining viable microorganisms. Usually, such devices comprise a container holding the medium, and a sampler capable of picking up a small portion of the pasty material and placing it within said container.

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US 5,149,506 discloses a device for collection and transportation of a stool sample which is composed of a container with a lid having a spoon secured to the underside of the lid, the container being filled with a liquid capable of maintaining microorganisms in a viable form.

5 US 4,559,839 discloses a stool collection and concentration receiver comprising a container holding a medium and including within it a collecting-filtering device comprising a stick for picking up the stool sample and sieve through which the diluted stool is filtered.

10 US 4,678,559 discloses a sampling vessel for pasty sample material comprising a sample-taking cup fitted on the lid of a container and facing towards the container's bottom.

In the above three patents the sampling member, used to pick the sample of the pasty material, is held *a priori* within the container holding also the preservation medium. This feature has the following problems:

15 - in order to sample the pasty material the container holding both the medium and the sampling member has to be opened, thus increasing the chances of contamination of the sterile medium by ambient atmosphere, or by the hands of the user and increases the possibility of spillage due to mishandling;

20 - once the sampling member is taken out of the medium filled container it may drip the medium on to its surrounding, and where the medium contains harmful ingredients, e.g. formaldehyde or mercury which are present in some preservation media, this may cause some damage if it comes into contact with the user's skin or eyes;

25 - the wet sampling member, once coming into contact with the pasty material sample, adds to the sample also a certain amount of the transport or suspension medium itself. This may be problematic if another sample of the pasty material is to be transferred into another container holding a different medium, since the second sample may already be
30 contaminated by the first medium.

A stool sample is typically subjected to two different tests one being a bacteriological test and the other a parasitological test. The medium

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required to maintain viable bacteria and the medium required to maintain viable parasites are not only different but are mutually exclusive, i.e. one type of medium damages the other type of microorganism. Thus, in the case of a pasty material which is to be sampled for the purpose of two or more different laboratory assay, such as stool, it would be preferable to provide a system for collection and transportation of pasty material which comprises two or more separate containers each one holding a different transport or suspension medium.

Finally, the above-mentioned prior art devices for collection and transportation of stool, do not address the problem of obtaining the original stool sample in a convenient manner which enables easy access to the user and the prior art tends to leave the solution to the problem to the skills of each user.

The present invention intends to provide an answer to some of the above-noted problems.

GENERAL DESCRIPTION OF THE INVENTION

The present invention provides a system for collecting, storing and transporting of specimens of a pasty material, comprising:

at least one container holding a preservation medium for preserving a chemical entity or living matter to be assayed in the specimen, the container being sealed by a pierceable membrane and having a closure arrangement for sealing the container after the membrane is pierced; and

a sampling device having a handle and at least one elongated specimen collecting member detachably attached thereto, the collecting member being adapted to be received within the container and having a pasty material retaining portion and a piercing tip for piercing the membrane at a lowermost end thereof remote from said handle, for piercing said film.

The system of the present invention is suitable for collecting, storing and transporting of any pasty material, for example, stools, food samples, e.g. soft cheese, yogurt, various spreads; soil samples, e.g. mud samples; and many others. With appropriate preservation media, the

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samples may be stored for a lengthy period of time prior to assaying for the chemical entity or living matter. The composition of the medium depends on the type of entity which should be preserved and subsequently assayed: for example, if the entity is a chemical substance, the medium will have a composition which ensure that the substance is preserved in a manner to avoid its deterioration; if the assayed entity is microorganism or any other living matter, the medium will be designed so as to maintain such microorganisms or other living matter in a viable condition. A system for collecting, storing and transporting specimens to subsequent assays for living matter, e.g. microorganisms, yeasts or parasites thereon, is a preferred embodiment of the invention. In accordance with a particularly preferred embodiment, the pasty material is stool.

At times a variety of different entities have to be assayed in the pasty material. This is the case, for example, in stool, where it is generally desired to assay both bacteria and parasites, which as noted above, require different media. A system for assaying a plurality of entities, which require different media, comprises at least two containers, each holding a different preservation medium, each suitable for different entities. The containers in such a system may be permanently attached to one another; or alternatively, the attachment of the two containers to one another being in a detachable fashion to allow detachment when the containers with the sample reaches the laboratory.

The closure arrangement is typically a rigid lid member attached to the container through a flexible linker.

The system further comprises a sampling device which is an element distinct and separate from the container. The provision of the container and a separate sampling device ensures that until the pasty material sample is introduced into the container, the medium therein is kept totally sterile. As already noted above, in prior art devices, where a sampling device was stored within the container, it was necessary to open the container prior to sampling, with an inevitable loss of sterility.

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The sampling device comprises a handle which is detachably connected to the at least one collecting member. The detachable connection can be by a breakable portion, by a fastener capable of holding or releasing an attachment element in the collecting member, etc. The at least one
5 collecting member is adapted to be received within corresponding at least one container. (It will be appreciated, that the number of collecting members will typically correspond to the number of containers, and where the containers are held together, the spacing between the collecting members will be made to correspond to the distance between the container such that
10 all collecting members may be inserted simultaneously to the respective containers).

Each collecting member has a piercing tip for piercing the container's pierceable membrane and has a pasty material retaining portion. Once the membrane is pierced by the piercing tip, the collecting member is
15 pushed down until the material retaining portion is accommodated within the container and embedded in the medium. Then, the handle is detached from the collecting member. As will be appreciated, there are a number of different constructions which have the capability of retaining a specimen of the pasty material: for example, a rough surface having multiple depressions
20 and/or protrusions; a helical structure; a ladder-like shaped structure having straight, curved or V-shaped ribs; a structure comprising a planar stem with protrusions, which may have the form of straight, curved or V-shaped ribs, or which may comprise a plurality of bulges, etc.

In order to ensure that the pasty material will be retained on the
25 retaining portion and will not be smeared on the membrane, it is preferable that the pasty material retaining portion has the widest cross-section at the lowermost part, near the piercing tip. This will ensure that the hole in the membrane which will be made by the piercing tip, will be sufficiently large to ensure free passage of the remaining portions of the collecting member.
30 In accordance with an embodiment of the invention, the pasty material retaining portion is defined by two lateral side walls which are wider than the pasty material retaining portion. Thus during insertion, only these side

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walls come into contact with the membrane, whereby the majority of the specimen of the pasty material does not come into contact with the membrane.

5 In accordance with a preferred embodiment of the invention, the sampling device comprises an integral disc with its surface being essentially perpendicular to the longitudinal axis of the collecting member. The shape of the disc is such that once the collecting member is introduced into the container, the disc is snugly retained within the inner walls of the container thus stabilizing the position of the collecting member within the container.

10 The disc preferably defines an opening which allows the insertion of a laboratory sampling device, e.g. a pipette, a sampling needle, etc, for withdrawing a portion of the specimen, this without a need to remove the collecting member with the integral disc.

As can be seen, the system of the invention minimize possible

15 contact between a sample and a laboratory technician, which is especially important in cases where the sample may contain hazardous materials or microorganisms.

In accordance with a preferred embodiment of the invention, as already noted above, the pasty material is stool. In accordance with this

20 embodiment, the system may comprise a stool collecting device, which has a collecting member for collecting an excreted stool sample and attachment members for attachment to a toilet seat. The stool collecting device also forms an independent aspect of the invention. The device is typically made of a sheet, e.g. a paper sheet, with the collecting portion and the attachment

25 member being integral, i.e. made of the same sheet. The attachment member may be a sheet portion adapted for wrapping around a toilet seat and are then retained by virtue of being sandwiched between the toilet seat and the upper edges of the toilet bowl. Alternatively, the attachment member may comprise adhesive patches on a bottom face of the attachment

30 member for adherence therethrough to the toilet seat. The adhesive patches are *a priori* protected with the protection being used prior to use and attachment thereof to the toilet seat.

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In accordance with an embodiment of the invention, the stool collecting member is a sheet portion suspended between the attachment members. Alternatively, the stool collecting member may have the form of a sack for collecting excreted stool sample. Such a sack may be provided
5 with openings at its bottom to allow a drainage of excreted fluid while retaining the stool.

The stool collecting device is preferably made of a flushable material, e.g. thin paper, and after use may be dropped into the toilet bowl to be flushed thereby.

10 The invention will now be further illustrated by the following description of a specific embodiment and by the annexed drawings. The illustrated embodiment concerns a system for collecting, storing and transporting stool samples. However, as will no doubt be appreciated by the artisan, this is an example only and the invention pertains also to systems for
15 collecting specimens of pasty material other than a stool.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an exploded view of a system of the invention comprising two containers and a sampling device with two corresponding collecting
20 members;

Fig. 2 shows the system, with the containers being assembled on a base and with the collecting member holding a stool sample;

Fig. 3 shows the system after combining the sampling device with the containers with the collecting member being inserted in the container;

25 **Fig. 4** shows the system after separating between the handle and the collecting members;

Fig. 5 shows the system after closing of the lid, ready for transportation into the laboratory;

Fig. 6 shows a stool collecting device in accordance with the invention;

30 **Figs. 7 and 8** show stool collecting devices in accordance with other embodiments of the invention, attached to a toilet seat.

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DESCRIPTION OF SPECIFIC EMBODIMENTS

Reference is first being made to Fig. 1, which is an exploded view showing the various components of the system, generally designated 10. The system 10 comprises two attached containers 12 and 12', a base member 14 with two receptacles 16 and 16' adapted to receive the bottom ends 18 and 18' of containers 12 and 12'; the system further comprises a sampling device 20 having a handle 22 and two collecting members 24 and 24'.

Containers 12 and 12' hold respective media 26 and 26', which may both be the same, but are typically different, e.g. one being a media for preserving bacteria and the other for parasites. Media 26 and 26' are typically semi-solid media, e.g. agar-based, but may also be a lipid, e.g. a culture media. Media 26 and 26' are contained in a portion of the containers sealed by pierceable membranes 28 and 28', the membranes being made of aluminum foil, a laminate of an aluminum foil and a plastic, (e.g. polyethylene) film, etc. Containers 12 and 12' are provided with respective lids 30 and 30' which are linked to the containers by means of linkers 32 and 32'. Sampling device 20 has integral disc members 34 and 34' at the upper end of specimen collecting members 24 and 24'. Disc 34 and 34' have each respective openings 35 and 35', the functions of which will be explained further below. Handle 22 is connected to disc members 34 and 34' by means of breakable neck portions 36 and 36' by small lateral respective movements of the handle and the collecting members connecting necks 36 and 36' break whereby handle 22 and collecting members 24 and 24' are separated.

Collecting members 24 and 24' are elongated and have each a piercing tip 38 and 38' at its bottom end adapted for piercing membranes 28 and 28'. Collecting members 24 and 24' have two lateral walls 40 and 40' which define the stool retaining portion consisting also of planar members 42 and 42' disposed within the lateral walls and carrying a plurality of V-shaped protrusions 44 and 44'. As can be seen, the collecting members

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have the largest cross-section at a portion adjacent piercing tips 38 and 38' thus the hole which is created in the membranes 28 and 28' allows easy passage therethrough for the remaining portions of the collecting members. Furthermore, lateral walls 40 and 40' ensure that the stool specimen held
5 on planar members 42 and 42' is not removed by the membranes 28 and 28' during passage of collecting members 24 and 24'.

In order to collect specimens of pasty material, collecting members 24 and 24' are inserted into a sample of the pasty material, e.g. stool, and thereby specimens are retained on collecting members 24 and 24'.
10 Sampling device 20 with stool specimens 50 and 50' retained on collecting members 24 and 24' is seen in Fig. 2. Also seen in this figure are containers 12 and 12' assembled on base member 14.

After collection of the specimens, the sampling device and the containers are combined by first pressing piercing tips 38 and 38' against
15 membranes 28 and 28' and then pushing the collecting members until they are accommodated within containers 12 and 12' with the collecting members being embedded within the medium containing the containers. Fig. 3 shows the sampling device 20 and containers 12 and 12' immediately after combining the two. As can be seen, the size of disc members 34
20 and 34' are such that they are accommodated snugly within the inner walls of the container stabilizing the collecting member in position.

At a next step shown in Fig. 4, the handle 22 is moved naturally thus breaking necks 36 and 36' leaving the collecting members within containers 12 and 12'. At a next step shown in Fig. 5, lids 30 and 30' are
25 used to close containers 12 and 12' and at this state the containers are shipped to the laboratory. In the laboratory, the lids are opened to a state similar to that shown in Fig. 4, and then a sampling device, e.g. a pipette, a bacteriologic needle, etc., is inserted through openings 35 and 35'. Thus, sampling of the specimen for laboratory testing does not require removal of
30 the collecting member, as in the case of prior art devices.

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A stool collecting device in accordance with an embodiment of the invention is shown in Fig. 6. The device, generally designated 60 is made of a sheet, e.g. paper, particularly thin paper which is flushable in a toilet. The device has a central collecting member, which is a portion of a sheet having the form of a sack, and has two attachment members 64 and 66 which are of a length such that their ends will reach two opposite sides of a toilet seat. The attachment members 64 and 66 have two adhesive patches 68 and 70, on bottom faces of the device. Adhesive patches 68 and 70 are *a priori* covered by a protective cover (now shown) and prior to use, the cover is removed and then these patches can adhere to the toilet seat. The device is fixed such that stool excreted by a person sitting on the toilet, falls into a sack-like collecting member 62 for later sampling by the sampling device. As can further be seen in Fig. 6, collecting member has at its bottom four openings 72 which are intended to allow a discharge of fluids which may be excreted together with the stool.

Two other embodiments of a stool collecting device are shown in Figs. 7 and 8, fixed to a toilet seat. The stool collecting device 80 shown in Fig. 7, is in principle similar to device 60 shown in Fig. 6 in that it comprises a central sack-like portion 82 and peripheral attachment flaps 84 and 86. Device 80 is fixed to a toilet seat 88 by means of adhesive patches, similarly as in the case of device 60 in Fig. 6.

Device 90 shown in Fig. 8, comprises a stool collecting portion 92 which is a sheet, e.g. made of paper, suspended between two attachment members 94 and 96 which are two flaps which are wrapped around two opposite sides of the toilet seat 98, and are fixed by virtue of being clamped between the toilet seat and the underlying toilet bowl (not shown). In addition a device of this embodiment may also comprise adhesive patches at the bottom face members of 94 and 96 to aid in fixing them to the toilet seat.

Having now finalized the description of the specific embodiment, the artisan will no doubt appreciate that the above specific embodiment is

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an example only and a myriad of other designs of the container and the sample device as well as the stool collecting device are possible, all being within the scope of the invention as defined in the appended claims.

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CLAIMS:

1. A system for collecting, storing and transporting of specimens of a pasty material, comprising:
 - 5 at least one container holding a preservation medium for preserving a chemical entity or living matter to be assayed in the specimen, the container being sealed by a pierceable membrane and having a closure arrangement for sealing the container after the membrane is pierced; and
 - 10 a sampling device having a handle and at least one elongated specimen collecting member detachably attached thereto, the collecting member being adapted to be received within the container and having a pasty material retaining portion and a piercing tip for piercing the membrane at a lowermost end thereof remote from said handle, for piercing said film.
2. A system according to Claim 1, wherein the medium is of a kind
15 which maintains living matter in a viable condition.
3. A system according to Claim 2, wherein the pasty material is stool.
4. A system according to Claim 1, comprising two containers, one holding a medium for bacteria and another for holding a medium for
20 parasites.
5. A system according to Claim 4, wherein the two containers are attached to one another.
6. A system according to Claim 4 or 5, wherein the sampling device comprises two specimen collecting members.
- 25 7. A system according to any one of the preceding claims, wherein said collecting member has a piercing tip for piercing the containers' pierceable membrane and has a pasty material retaining portion.
8. A system according to Claim 7, wherein the pasty material retaining portion has the widest cross-section at a lowermost part thereof,
30 near the piercing tip.

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9. A system according to any one of the preceding claims, wherein the sampling device comprises an integral disc in an upper end of the collecting member, with its surface being essentially perpendicular to the longitudinal axis of the collecting member.
- 5 10. A system according to Claim 9, wherein the shape of the disc is such that once the collecting member is introduced into the container, the disc is snugly retained within the inner walls of the container.
11. A system according to Claim 10, wherein the disc defines an opening which once the collecting member is placed within the container,
10 allows insertion of a laboratory sampling device into the medium, without a need to remove the collecting member.
12. A stool collecting device which has a collecting member for collecting an excreted stool sample and attachment members for attachment to a toilet seat.
- 15 13. A device according to Claim 11, made of a sheet with a stool collecting portion and integral flats for attachment to a toilet seat.
14. A device according to Claim 12, comprising adhesive patches for fixing the device into a toilet seat.
15. A system according to any one of Claims 1-10, comprising a
20 stool collecting device according to any one of Claims 11-13.

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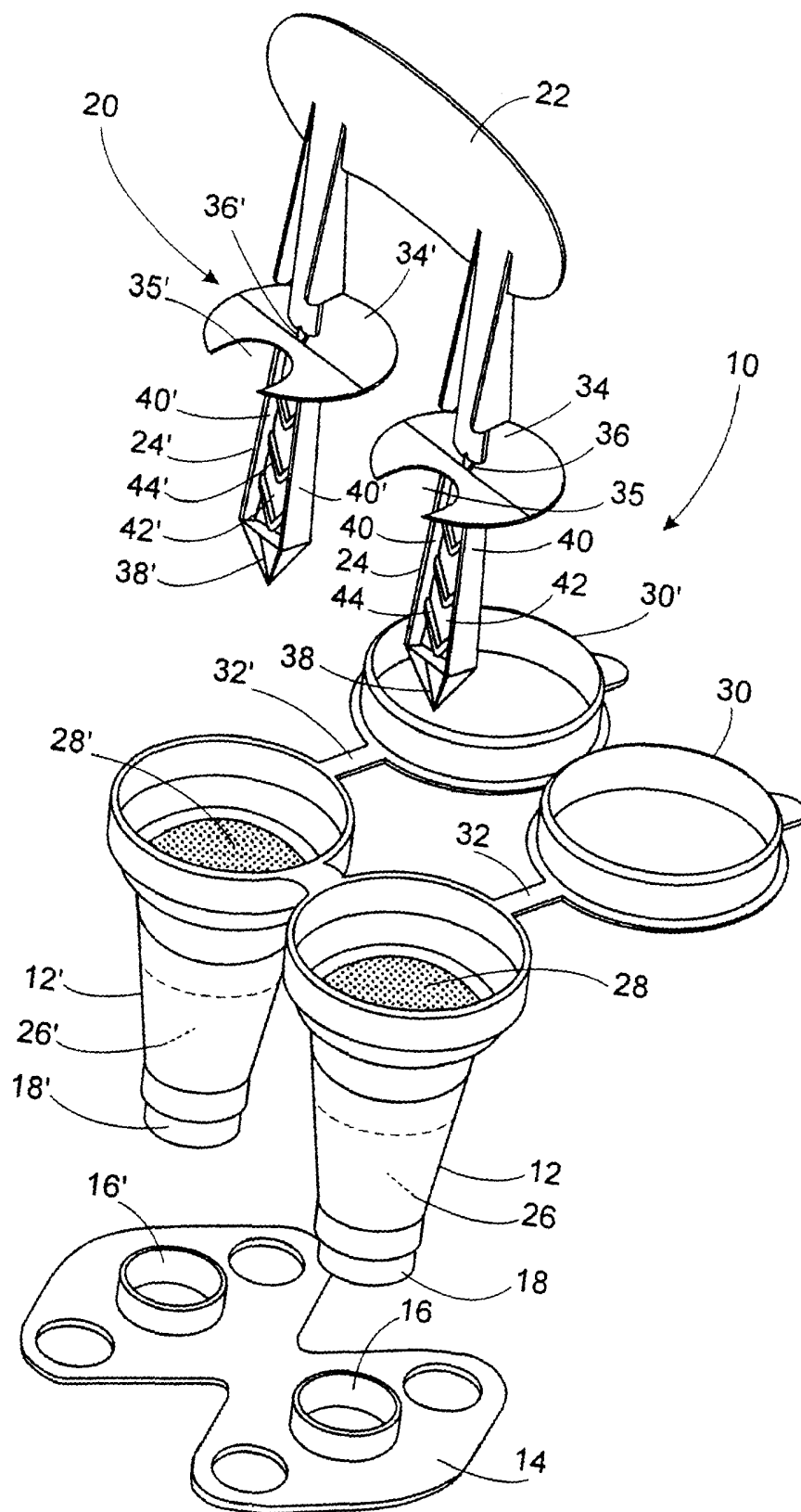


Fig. 1

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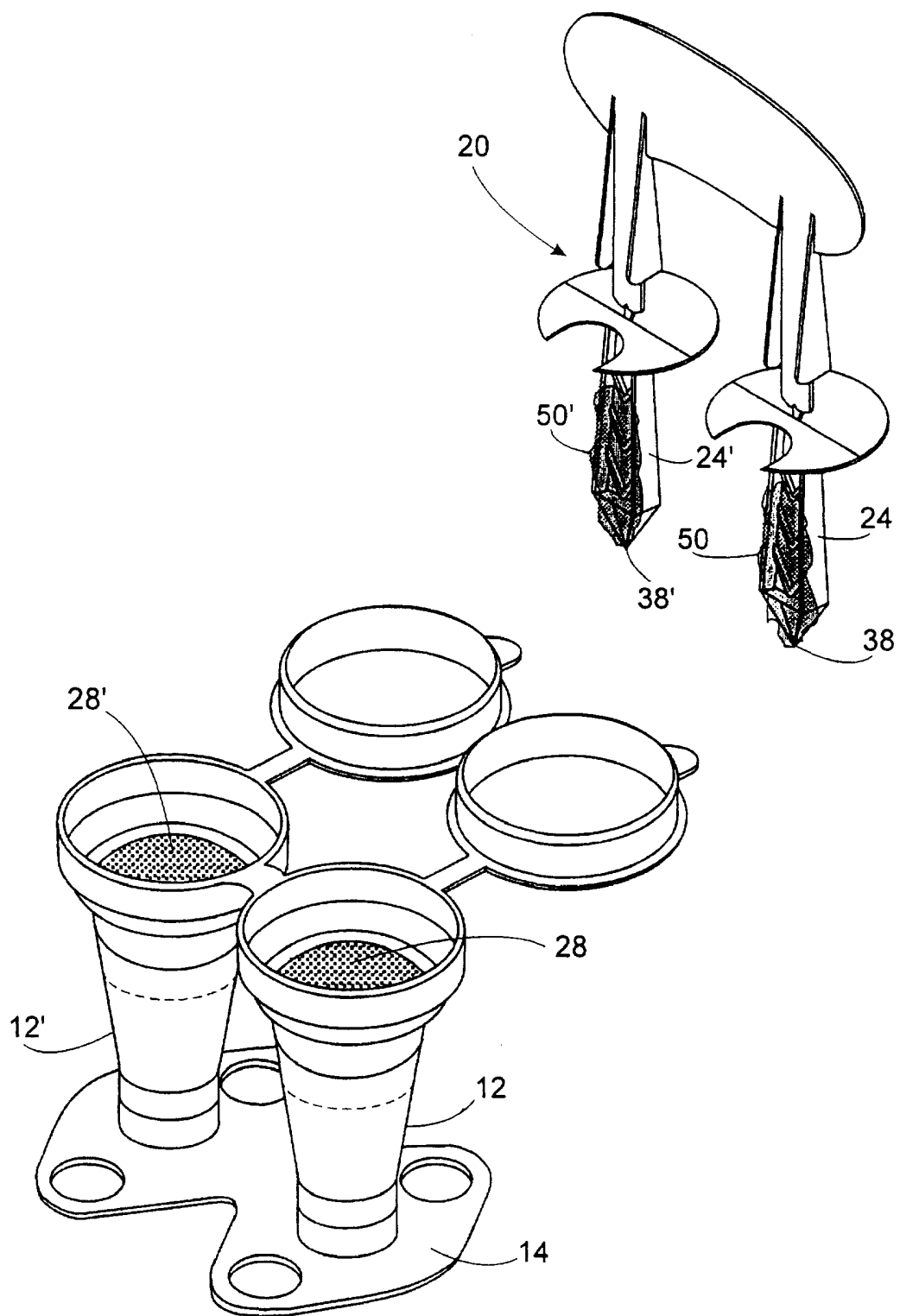


Fig. 2

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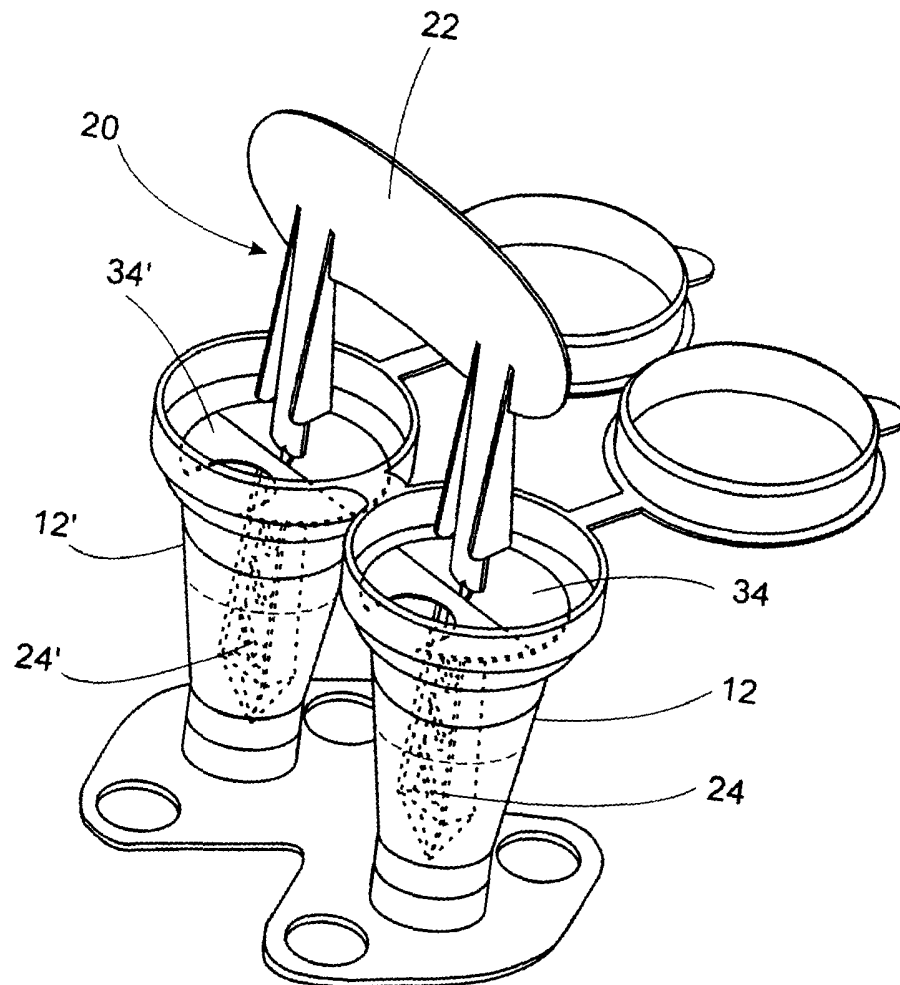


Fig. 3

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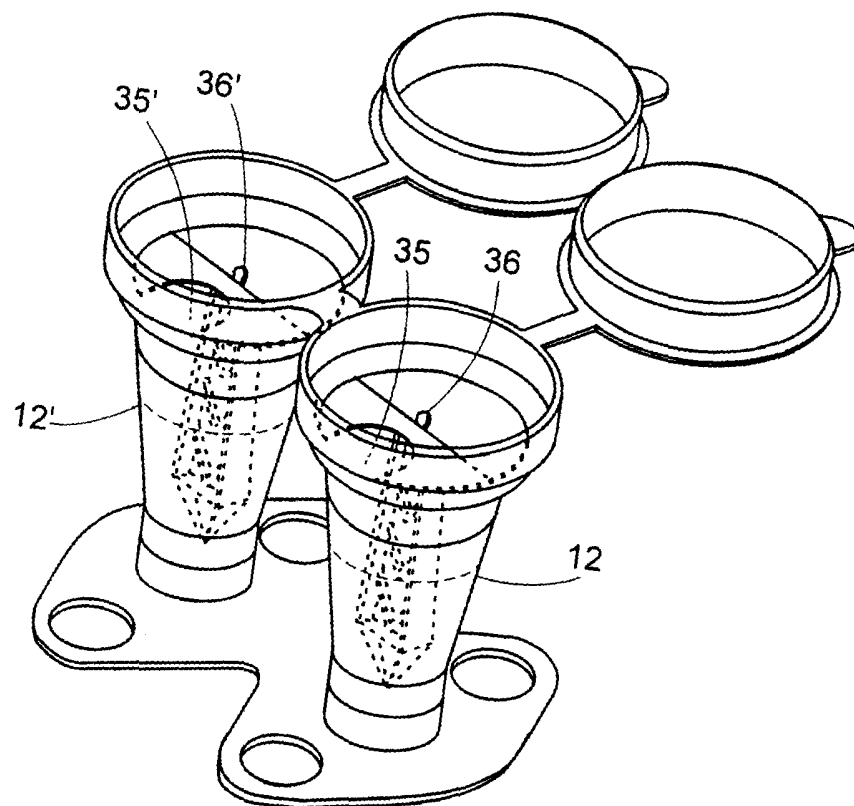


Fig. 4

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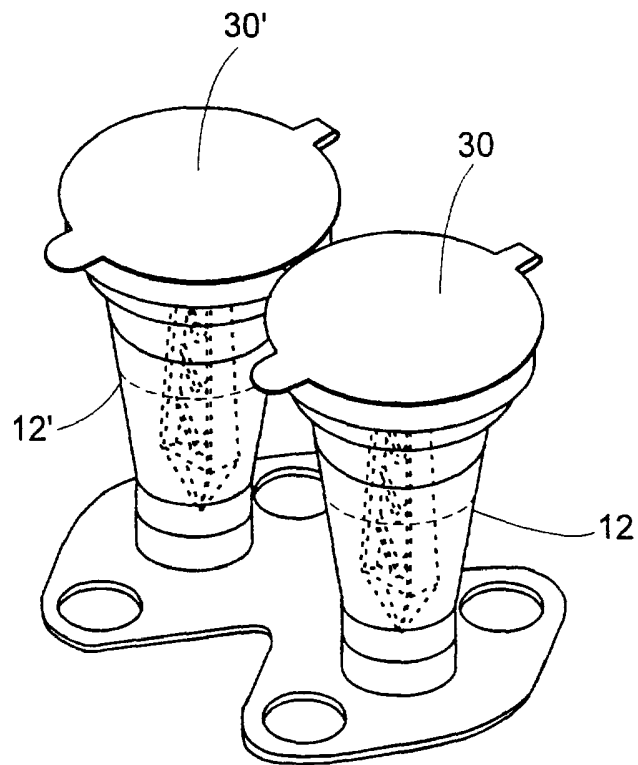


Fig. 5

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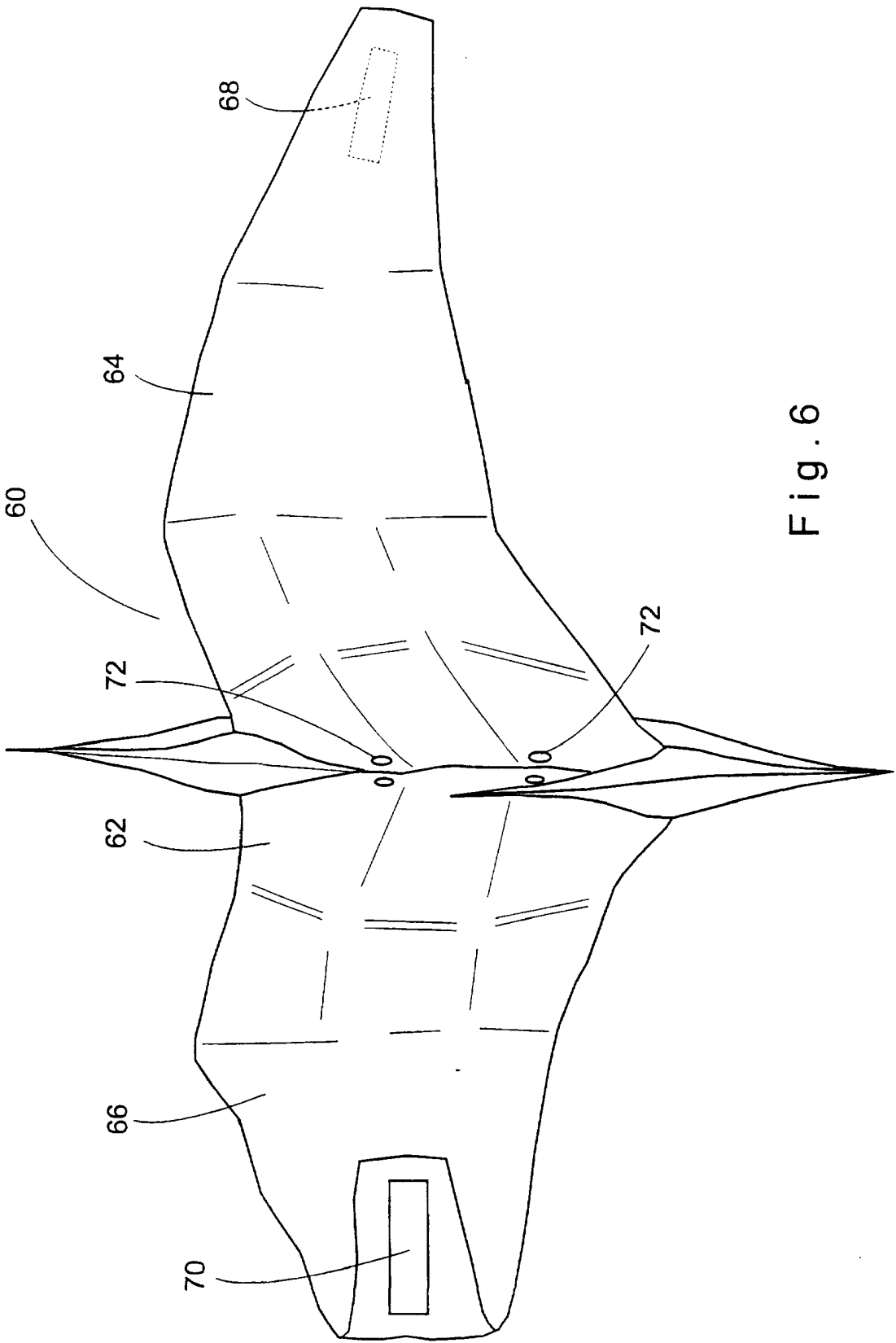


Fig. 6

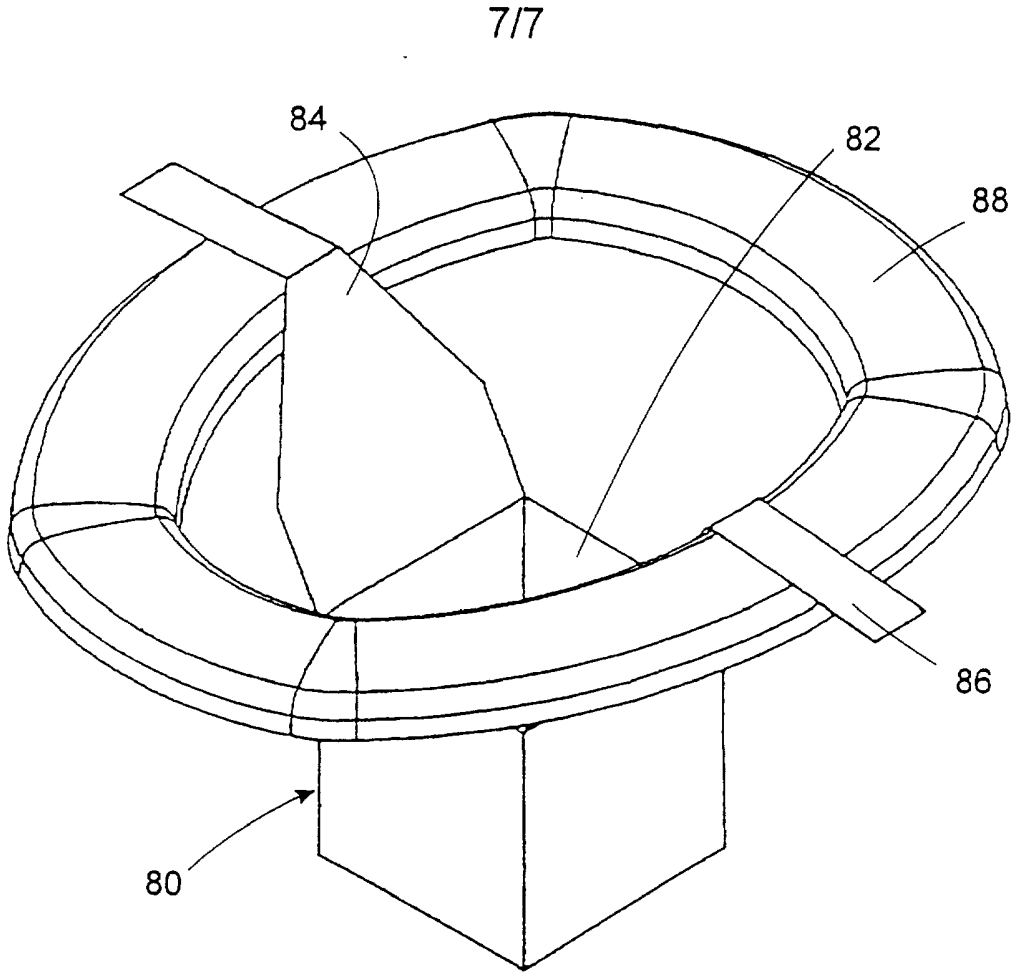


Fig. 7

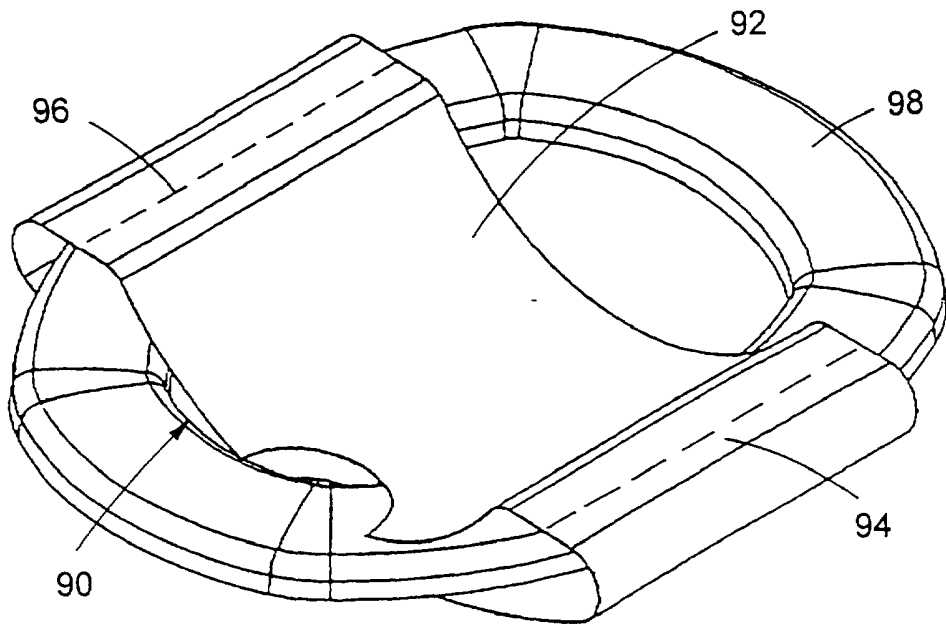


Fig. 8