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(54) **Wedge-shaped port for flexible containers.**

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Description

The invention generally relates to ports for containers and more specifically relates to wedge-shaped ports for flexible containers.

It is common medical practice to provide fluids to a patient either intravenously or enterally as a method of treating a patient for various medical conditions. Frequently, the fluids to be administered to a patient are contained in a flexible container. One method of forming a flexible container is to seal two sheets of flexible material about the periphery of the sheets to create a cavity. A port is frequently placed between the sheets during the sealing process to create a communication between the cavity and the exterior of the container to provide a means of introducing fluid into or dispensing fluid from the container. In many cases, a length of flexible tubing is typically attached to this port so that a needle or enteral feeding tube can then be attached to the other end of the tube to administer the fluid to the patient.

Generally speaking, fluids that are administered to a patient must be sterile. Therefore, it is very important that a hermetic seal is created between the port and the container. Certain medical solutions that are administered to patients such as high concentrations of dextrose, amino acids, lipid emulsions, or enteral diets are also oxygen sensitive. Therefore, in those cases, it is also very important that the container and the port are manufactured from materials that reduce permeability of the container, or as an alternative, an overwrap is placed over the container at the time of manufacture to reduce permeability of the container.

Typically fluids to be administered to a patient are added to a flexible container through the use of an access port into the container. A separate port is frequently provided to administer the fluid to the patient. In the past, these ports have been typically formed by placing a tube in between the sheets of the container as the container is manufactured. The tubes are sealed to both sheets of the container during manufacture. Since the tubes have a cylindrical shape and the sheets are basically flat, stresses, and thinning occur in the sheets as the sheets are sealed about each tubular port. One means of reducing the stresses created by sealing a tubular port to the sheets of a flexible container is to design the port to have an lenticular rather than cylindrical configuration.

US-A-4078699 describes a package which includes a closed pouch-type container of flexible material with fluid contents. One portion of the container is formed into a pocket for sealingly receiving a dispenser assembly. When assembled to the container, an insert conduit penetrates the innermost portion of the pocket and communicates

with the contents of the container for dispensing the same. In use, a spike is inserted into an elongated tube and penetrates the seal or edge of the container, with the concomitant risk that it may puncture a side wall.

One problem with each of the examples described above, however, is that thinning and stressing of the sheets continues to occur as the flat sheets are forced to seal about a curved port. As long as the material used to create the container is fairly elastic and capable of withstanding stresses, then it is possible to develop an adequate seal between a curved port and a flat sheet. However, in many cases, it is desired to use materials which are relatively inelastic or are very thin and thus more susceptible to stress fractures at the location of the seal of the material to the curved port.

The invention which is defined in claim 1, can be briefly described as a container formed from one or more sheets of material and having a seal formed about the periphery to form a cavity. The invention further includes a port in communication with the cavity of the container. The port has a wedge shape with at least one orifice therethrough. The wedge includes a base and first and second oppositely disposed substantially flat sides which extend from the base. The first and second sides form an acute angle. The port includes an orifice that forms a passageway from the base toward the acute angle into the cavity of the container. The port is located between the sheets of material along the seal so that the port is in sealed engagement with the material. The port is disposed in the container such that the acute angle is located within the cavity of the container and the base is located outside the cavity.

FIG. 1 is an isometric drawing of one embodiment of the invention as sealed within a container;

FIG. 2 is an isometric view of a wedge-shaped port including a flap;

FIG. 3 is an isometric view of a port including a removable cover;

FIG. 4 is an isometric view of a port in which the material forming the container extends beyond the base of the port;

FIG. 5 is a top view, partially broken away, of a wedge-shaped port having a breakable seal surrounding the base of the wedge;

FIG. 6 is an isometric view of a "U-shaped" embodiment of the port of the subject invention;

FIG. 7 is an embodiment of the invention containing a plurality of orifices in a wedge-shaped port; and

FIG. 8 illustrates an embodiment of the invention in which opposite sides of a wedge-shaped port may flex outwardly.

Referring now to FIG. 1, a flexible container 10 is formed of at least one sheet of flexible material 12. The container is sealed about the edges 14 of the material to form a cavity 16 within the container. A wedge shaped port 18 is located at the bottom of the container. The wedge shaped port has at least one orifice 20 therethrough. The wedge includes a base 22 and first and second oppositely disposed substantially flat sides 24 and 26 extending therefrom. The first and second sides form a generally acute angle 28 which creates a relatively thin edge 30 along the top of the wedge. In a preferred embodiment of the invention, the port is located between the first and second sheets of material 14 and 16 along a seal line 32. The port is disposed in the container such that the acute angle 28 is located within the cavity of the container in the base 22 is located outside of the cavity.

In a preferred embodiment of the invention, at least one sheet of the container may extend downwardly from the base of the wedge to form a flap 34 to cover the orifice 20 at the base 22. The flap may be removably sealed to the base 22 of the wedge 18. In the embodiment illustrated in FIG. 2, a flap 36 may include a first portion 38 which covers the base of the wedge 18 and a second portion 40 which can be folded up over a side 24 of the wedge 18. In many embodiments of the invention, it is desirable for the flap to be temporarily sealed to the base of the wedge in order to maintain cleanliness or sterility of the orifice or to control permeability. In such embodiments, when a user wishes to insert a tube into the port to either add or remove fluid from the container, the user can simply peel back the flap from the port immediately prior to insertion of the tube. In other embodiments, the cover may be formed of an elastomeric resealable material.

In another embodiment of the invention, it may be desirable to permanently seal flap 34 as illustrated in FIG. 1 (or flap 36 as illustrated in FIG. 2) to the base or side wall of the wedge 18. In this embodiment, the flap forms a penetratable membrane which can be ruptured by the user through the use of a spiked tube or needle.

In yet another embodiment of the invention, the port 18 may include a removable cover 42 as illustrated in FIG. 3. As can be seen in the figure, the removable cover 42 covers the base 22 of the wedge 18 and third and fourth side walls 44 and 46 of the wedge. The sidewalls 44 and 46 preferably include two triangular portions 44A and 46A that taper in conformity with the angle 28 and that are outwardly bent so as to extend from the sidewalls 44 and 46, respectively, and to define an angle therebetween. Sidewalls 42A and 42B of the cover would thus conform in shape to the sidewalls 44 and 46 and their respective outwardly bent portions

44A and 46A. In one embodiment of the invention, the removable cover can include an adhesive coating to create a temporary bond between the cover and the base of the wedge. This insures that the removable cover will stay on the wedge-shaped port until the user wishes to remove the cover to either introduce fluids or remove fluids from the container.

In another embodiment of the invention as illustrated in FIG. 4, the container may include extensions 48 and 50 which extend beyond the base of the wedge-shaped port from each side 24 and 26 of the wedge. It may be desirable to include such extensions 48 and 50 to provide protection for a spike or needle which may be inserted into the port. It may also be desirable to include such extensions on both sides of the wedge to create a sealed enclosure 52 about the base of the wedge as illustrated in FIG. 5.

The side walls 24 and 26 may be generally solid walls as illustrated in FIG. 1 or may be generally "U-shaped" walls as illustrated in FIG. 6 thereby defining two triangular or substantially triangular legs 44B and 46B comprising portions of the sides 24 and 26 and the triangular or substantially triangular extensions 44A and 46A, respectively. The size and thickness of the side walls will, of course, vary depending on the size of the container and the application for which the container is being used. However, generally speaking, it is desirable that the third and fourth side walls 44 and 46 be somewhat thicker than the first and second side walls 24 and 26 when it is desired to minimize oxygen ingress into the cavity of the container. In the preferred embodiment of the invention, the first and second walls will generally be from 2.54×10^{-5} to 2.54×10^{-2} m thick and the third and fourth walls will generally be from 2.54×10^{-5} to 2.54×10^{-2} m thick.

The acute angle 28 may likewise vary depending on the use and size of the container or the size of any spiking device that may be used with the container. In general, however, it is preferable that the acute angle range from 1 to 89 degrees.

The wedge-shaped port can be formed from a variety of materials. In general, the main requirement for the material from which the port is formed is that it is capable of forming a hermetic seal with the material from which the container is made. In many embodiments, it is preferable that the port be formed from a material which has low permeability to oxygen and is sterilizable using standard sterilization techniques. Some of the preferred materials to use for the port are polyethylene, polypropylene or polyolefin or any of the materials listed above blended with ethylene vinyl alcohol, polyvinylidene chloride, or nylon. In one embodiment of the invention, it may be desirable to pro-

vide a metalized coating on the third and fourth walls 44 and 46 of the port to further reduce permeability of those walls.

In another embodiment of the invention, the orifice 20 may include a membrane 58 which extends across the entire orifice as illustrated in FIG. 1 to form a piercable seal. The membrane creates a barrier between the cavity of the container and the exterior to maintain the cleanliness (or sterility) of the contents of the container prior to use. The membrane also prevents the fluids from leaking from the container.

In still yet another embodiment of the invention, the wedge-shaped port may include multiple orifices 54 and 56 as illustrated in FIG. 7. In another embodiment of the invention each orifice may include a conduit 60 which extends beyond the base of the orifice 54 as also illustrated in FIG. 7. The conduit may serve several purposes, for instance, the conduit may support a spike inserted in the port. The conduit may also provide a location for attaching a piercable medication membrane or sterility cover. The conduit may also be useful for attaching flexible tubing to the port.

As can be seen in FIG. 3, in one embodiment of the invention the first and second sides 24 and 26 may extend beyond the third and fourth sides 44 and 46 to create a channel 62 on either side of the wedge shaped port. This channel may be useful as a means for conveying the wedge-shaped port during manufacture of the container.

Referring now to FIG. 8, in another embodiment of the invention the first and second side walls 24 and 26 are so arranged and constructed that when a spike (70) is inserted into the orifice 54 of the port, the side walls 24 and 26 will flex outwardly. This embodiment is desirable to promote complete drainage of fluid from the container because the outward flexure of the side walls also causes the walls of the container to separate from one another to allow fluid to more readily flow into the port.

Claims

1. A container (10) formed out of at least one sheet of material (12) folded and sealed along a seal line (32) at the superimposed edges (14) of the sheet(s) to form a cavity (16) for housing a fluid, said container comprising a wedge-shaped port (18) which is disposed in sealed engagement with said edges (14), said port having a base (22), two inclined side walls (24, 26) laying in two planes intersecting at an acute angle (28) at the vertex (30) of the wedge, and two lateral walls (44, 46) perpendicularly delimited by said inclined side walls, said port being so disposed that said base (22)

faces outwards from the container and said vertex (30) faces inwards into the container, and wherein an orifice (20) is formed through said base extending to the vertex of the port so as to allow the insertion of a spike (70) for establishing a sealed fluid communication between the cavity and an external conduit, characterized in that said lateral walls (44, 46) include triangular portions (44A, 46A) that taper in conformity with the acute angle (28) and extend beyond said inclined side walls (24, 26) to form triangular legs (44B, 46B) comprising portions of the side walls (24, 26) which lie in said intersecting planes and against which spreadable portions of said superimposed edges (14) are sealed along a line which forms a part of the seal line (32), so that the spike (70), when inserted into said orifice, does not penetrate the sheet of material (12).

2. A container as recited in claim 1, wherein at least one side of said material (12) extends beyond said base (22) of said port (18) to form a flap (34) to cover said orifice (20) at said base.
3. A container as recited in claim 2, wherein said flap is removably sealed to said base.
4. A container as recited in claim 2, wherein said flap is permanently sealed to said base.
5. A container as recited in claim 2, wherein two sides of said material extend beyond said base.
6. A container as recited in any preceding claim, wherein said inclined side walls (24, 26) are generally "U" shaped.
7. A container as recited in any preceding claim, wherein said port further includes multiple orifices (54, 56) which individually form passageways from said base (22) to said vertex (30).
8. A container as recited in any preceding claim, wherein said port is formed of a material having low permeability to oxygen.
9. A container as recited in claim 8, wherein said port is formed of polyethylene, polypropylene or a polyolefin.
10. A container as recited in any preceding claim, wherein said lateral walls (44, 46) are thicker than said inclined side walls (24, 26).

11. A container as recited in any preceding claim, wherein said inclined side walls (24, 26) are from 2.54×10^{-5} to 2.54×10^{-2} m thick and said lateral walls are from 2.54×10^{-5} to 2.54×10^{-2} m thick. 5
12. A container as recited in any preceding claim, wherein said acute angle (28) ranges from one to 89 degrees. 10
13. A container as recited in any preceding claim, wherein said orifice (20) includes a membrane (58) to form a pierceable seal across said orifice. 15
14. A container as recited in any preceding claim further including at least one conduit (60) extending from at least one of said orifices. 20
15. A container as recited in any preceding claim, wherein said inclined side walls (24, 26) extend beyond said lateral walls (44, 46). 25
16. A container as recited in any preceding claim, wherein said inclined side walls (24, 26) are so constructed and arranged that they flex outwardly when a spike is inserted into said cavity through said orifice. 30
17. A container as recited in any preceding claim, wherein said lateral walls (44, 46) have outer surfaces with a coating to control permeability of the port. 35
18. A container as recited in any preceding claim comprising a removeable cover (42) surrounding said base. 40
19. A container as recited in claim 18, wherein said removeable cover is formed from a material having low permeability. 45
20. A container as recited in claim 18 or claim 19, wherein said removeable cover further covers said lateral walls (44, 46). 50
21. A container as recited in claim 18, 19 or 20, wherein said removeable cover includes an adhesive coating for removeable attachment to said base. 55
22. A container as recited in any one of claims 18-21, wherein said removeable cover is formed of an elastomeric resealable material.

Patentansprüche

1. Behälter (10), der aus zumindest einer Materiallage (12) gebildet ist, die entlang einer Versiegelungslinie (32) an den übereinanderliegenden Rändern (14) der Lage(n) gefaltet und abgedichtet ist, um einen Hohlraum (16) zur Aufnahme einer Flüssigkeit zu bilden, wobei der Behälter einen keilförmigen Auslaß (18) aufweist, der mit den Rändern (14) in Abdichtungseingriff steht, wobei der Auslaß eine Basis (22), zwei geneigte Querwände (24, 26), die in zwei Ebenen liegen, welche sich unter einem spitzen Winkel (28) am Scheitel (30) des Keiles schneiden, und zwei Seitenwände (44, 46) aufweist, die durch die geneigten Querwände senkrecht begrenzt werden, wobei der Auslaß so angeordnet ist, daß die Basis (22) vom Behälter nach außen und der Scheitel (30) in den Behälter hinein weist, und wobei in dieser Basis eine Öffnung (20) ausgebildet ist, die sich zum Scheitel des Auslasses hin erstreckt, um das Einführen eines Dornes (70) zur Erzeugung einer abgedichteten Flüssigkeitsverbindung zwischen dem Hohlraum und einer äußeren Leitung zu ermöglichen, dadurch gekennzeichnet, daß die Seitenwände (44, 46) dreieckige Teile (44A, 46A) aufweisen, die sich gemäß dem spitzen Winkel (28) verjüngen und über die geneigten Querwände (24, 26) hinausragen, um dreieckige Schenkel (44B, 46B) zu bilden, welche Teile der Seitenwände (24, 26) umfassen, die in den schneidenden Ebenen liegen und gegen welche spreizbare Teile der übereinanderliegenden Ränder (14) entlang einer Linie abgedichtet sind, die einen Teil der Versiegelungslinie (32) bildet, so daß der Dorn (70) beim Einführen in die Öffnung die Materiallage (12) nicht durchbohrt.
2. Behälter nach Anspruch 1, bei welchem zumindest eine Seite des Materiales (12) über die Basis (22) des Auslasses (18) hinausragt, um eine Verschußlasche (34) zum Abdecken der Öffnung (20) an der Basis zu bilden.
3. Behälter nach Anspruch 2, bei welchem die Verschußlasche entfernbar an die Basis gesiegelt ist.
4. Behälter nach Anspruch 2, bei welchem die Verschußlasche permanent an die Basis gesiegelt ist.
5. Behälter nach Anspruch 2, bei welchem zwei Seiten des Materials über die Basis hinausragen.

6. Behälter nach einem der vorhergehenden Ansprüche, bei welchem die geneigten Querwände (24, 26) allgemein U-förmig sind.
7. Behälter nach einem der vorhergehenden Ansprüche, bei welchem der Auslaß ferner mehrere Öffnungen (54, 56) aufweist, die individuell Durchgänge von der Basis (22) zum Scheitel (30) bilden.
8. Behälter nach einem der vorhergehenden Ansprüche, bei welchem der Auslaß aus einem Material mit geringer Sauerstoffdurchlässigkeit gebildet ist.
9. Behälter nach Anspruch 8, bei welchem der Auslaß aus Polyethylen, Polypropylen oder einem Polyolefin gebildet ist.
10. Behälter nach einem der vorhergehenden Ansprüche, bei welchem die Seitenwände (44, 46) dicker sind als die geneigten Querwände (24, 26).
11. Behälter nach einem der vorhergehenden Ansprüche, bei welchem die geneigten Querwände (24, 26) eine Dicke von $2,54 \times 10^{-5}$ bis $2,54 \times 10^{-2}$ m und die Seitenwände eine Dicke von $2,54 \times 10^{-5}$ bis $2,54 \times 10^{-2}$ m aufweisen.
12. Behälter nach einem der vorhergehenden Ansprüche, bei welchem der spitze Winkel (28) 1° bis 89° beträgt.
13. Behälter nach einem der vorhergehenden Ansprüche, bei welchem die Öffnung (20) eine Membran (58) aufweist, die eine durchstechbare Abdichtung über der Öffnung bildet.
14. Behälter nach einem der vorhergehenden Ansprüche, der ferner zumindest ein Leitungsstück (60) aufweist, das sich von zumindest einer der Öffnungen wegerstreckt.
15. Behälter nach einem der vorhergehenden Ansprüche, bei welchem die geneigten Querwände (24, 26) über die Seitenwände (44, 46) hinausragen.
16. Behälter nach einem der vorhergehenden Ansprüche, bei welchem die geneigten Querwände (24, 26) so ausgebildet und angeordnet sind, daß sie sich nach außen biegen, wenn ein Dorn durch die Öffnung in den Hohlraum eingeführt wird.
17. Behälter nach einem der vorhergehenden Ansprüche, bei welchem die Seitenwände (44,

46) Außenflächen mit einer Beschichtung zur Kontrolle der Durchlässigkeit der Auslaßöffnung aufweisen.

18. Behälter nach einem der vorhergehenden Ansprüche, der eine entfernbare, die Basis umgebende Abdeckung (42) aufweist.
19. Behälter nach Anspruch 18, bei welchem die entfernbare Abdeckung aus einem Material mit geringer Durchlässigkeit gebildet ist.
20. Behälter nach Anspruch 18 oder 19, bei welchem die entfernbare Abdeckung ferner die Seitenwände (44, 46) bedeckt.
21. Behälter nach Anspruch 18, 19 oder 20, bei welchem die entfernbare Abdeckung eine Klebstoffbeschichtung zur lösbaren Befestigung an der Basis aufweist.
22. Behälter nach einem der Ansprüche 18 bis 21, bei welchem die entfernbare Abdeckung aus einem elastomeren, wiederversiegelbaren Material gebildet ist.

Revendications

1. Récipient (10) formé d'au moins une feuille de matière (12) pliée et scellée le long d'une ligne de joint (32) aux bords superposés (14) de la feuille ou des feuilles pour former une cavité (16) destinée à contenir un fluide, ledit récipient comprenant un embout (18) en forme de coin qui est disposé en engagement étanche avec lesdits bords (14), ledit embout ayant une base (22), deux parois inclinées (24, 26) de côté s'étendant dans deux plans en intersection en formant un angle aigu (28) au sommet (30) du coin, et deux parois latérales (44, 46) délimitées perpendiculairement par lesdites parois inclinées de côté, ledit embout étant disposé de façon que ladite base (22) soit tournée vers l'extérieur depuis le récipient et que ledit sommet (30) soit tourné vers l'intérieur du récipient, et dans lequel un orifice (20) est formé à travers ladite base, s'étendant jusqu'au sommet de l'embout afin de permettre l'insertion d'une pointe (70) pour établir une communication de fluide étanche entre la cavité et un conduit extérieur, caractérisé en ce que lesdites parois latérales (44, 46) comprennent des parties triangulaires (44A, 46A) qui s'effilent en conformité avec l'angle aigu (28) et s'étendent au-delà desdites parois de côté inclinées (24, 26) pour former des branches triangulaires (44B, 46B) comprenant des parties des parois de côté (24, 26) qui s'étendent

- dans lesdits plans en intersection et contre lesquelles des parties desdits bords superposés (14), pouvant être écartées, sont appliquées de façon étanche suivant une ligne qui forme une partie de ladite ligne de joint (22), afin que la pointe (70), lorsqu'elle est insérée dans ledit orifice, ne pénètre pas dans la feuille de matière (12).
2. Récipient selon la revendication 1, dans lequel au moins un côté de ladite matière (12) s'étend au-delà de ladite base (22) dudit embout (18) pour former un rabat (34) destiné à recouvrir ledit orifice (20) à ladite base.
 3. Récipient selon la revendication 2, dans lequel ledit rabat est scellé de façon amovible à ladite base.
 4. Récipient selon la revendication 2, dans lequel ledit rabat est scellé de façon permanente à ladite base.
 5. Récipient selon la revendication 2, dans lequel deux côtés de ladite matière s'étendent au-delà de ladite base.
 6. Récipient selon l'une quelconque des revendications précédentes, dans lequel lesdites parois de côté inclinées (24, 26) sont de forme globalement en "U".
 7. Récipient selon l'une quelconque des revendications précédentes, dans lequel ledit embout présente en outre des orifices multiples (54, 56) qui forment individuellement des passages depuis ladite base (22) jusqu'audit sommet (30).
 8. Récipient selon l'une quelconque des revendications précédentes, dans lequel ledit embout est formé d'une matière ayant une faible perméabilité à l'oxygène.
 9. Récipient selon la revendication 8, dans lequel ledit embout est formé de polyéthylène, de polypropylène ou d'une polyoléfine.
 10. Récipient selon l'une quelconque des revendications précédentes, dans lequel lesdites parois latérales (44, 46) sont plus épaisses que lesdites parois de côté inclinées (24, 26).
 11. Récipient selon l'une quelconque des revendications précédentes, dans lequel lesdites parois de côté inclinées (24, 26) ont une épaisseur comprise entre 2.54×10^{-5} à 2.54×10^{-2} m et lesdites parois latérales ont une épaisseur comprise entre 2.54×10^{-5} et 2.54×10^{-2} m.
 12. Récipient selon l'une quelconque des revendications précédentes, dans lequel ledit angle aigu (28) est compris entre 1 et 89 degrés.
 13. Récipient selon l'une quelconque des revendications précédentes, dans lequel ledit orifice (20) comprend une membrane (58) destinée à former un opercule pouvant être percé, à travers ledit orifice.
 14. Récipient selon l'une quelconque des revendications précédentes, comprenant en outre au moins un conduit (60) s'étendant à partir d'au moins l'un desdits orifices.
 15. Récipient selon l'une quelconque des revendications précédentes, dans lequel lesdites parois de côté inclinées (24, 26) s'étendent au-delà desdites parois latérales (44, 46).
 16. Récipient selon l'une quelconque des revendications précédentes, dans lequel lesdites parois de côté inclinées (24, 26) sont réalisées et agencées de manière qu'elles fléchissent vers l'extérieur lorsqu'une pointe est insérée dans ladite cavité à travers ledit orifice.
 17. Récipient selon l'une quelconque des revendications précédentes, dans lequel lesdites parois latérales (44, 46) ont des surfaces extérieures portant un revêtement pour limiter la perméabilité de l'embout.
 18. Récipient selon l'une quelconque des revendications précédentes, comportant un couvercle amovible (42) entourant ladite base.
 19. Récipient selon la revendication 18, dans lequel ledit couvercle amovible est formé d'une matière à faible perméabilité.
 20. Récipient selon la revendication 18 ou la revendication 19, dans lequel ledit couvercle amovible couvre en outre lesdites parois latérales (44, 46).
 21. Récipient selon la revendication 18, 19 ou 20, dans lequel ledit couvercle amovible comprend un revêtement d'adhésif pour être fixé de façon amovible à ladite base.
 22. Récipient selon l'une quelconque des revendications 18-21, dans lequel ledit couvercle amovible est formé d'une matière élastomérique pouvant être réobturée.

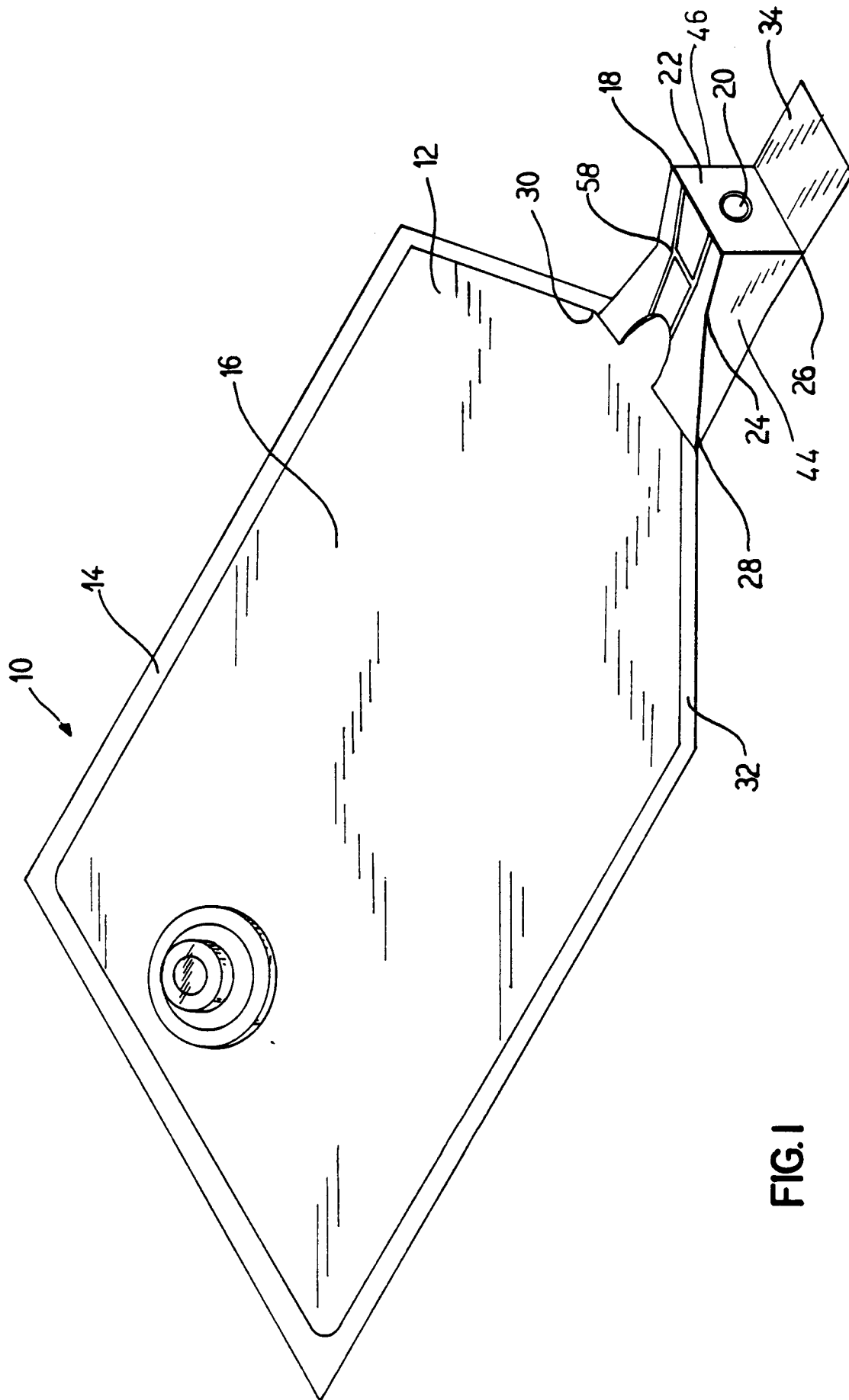


FIG. 1

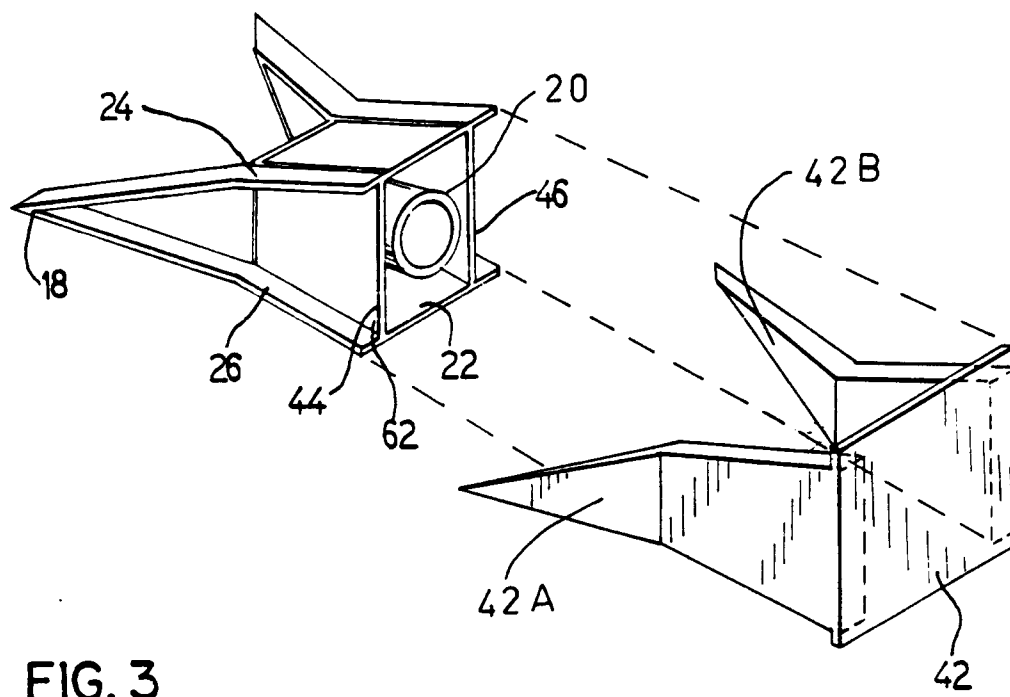
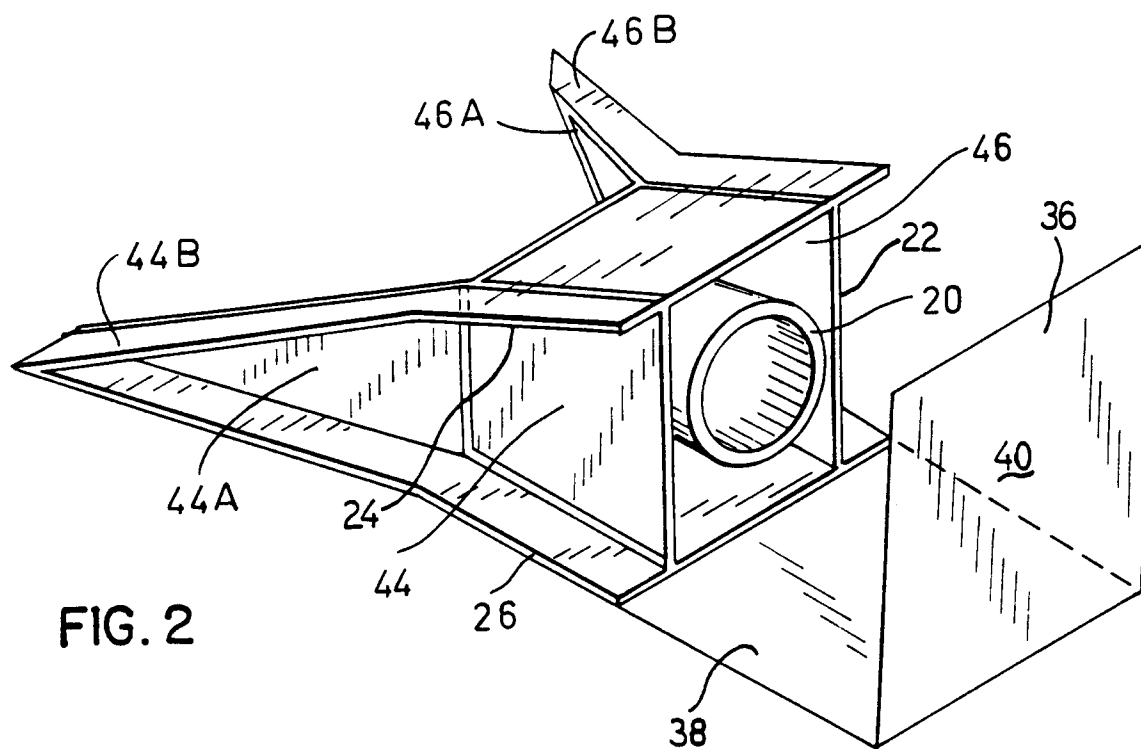


FIG. 4

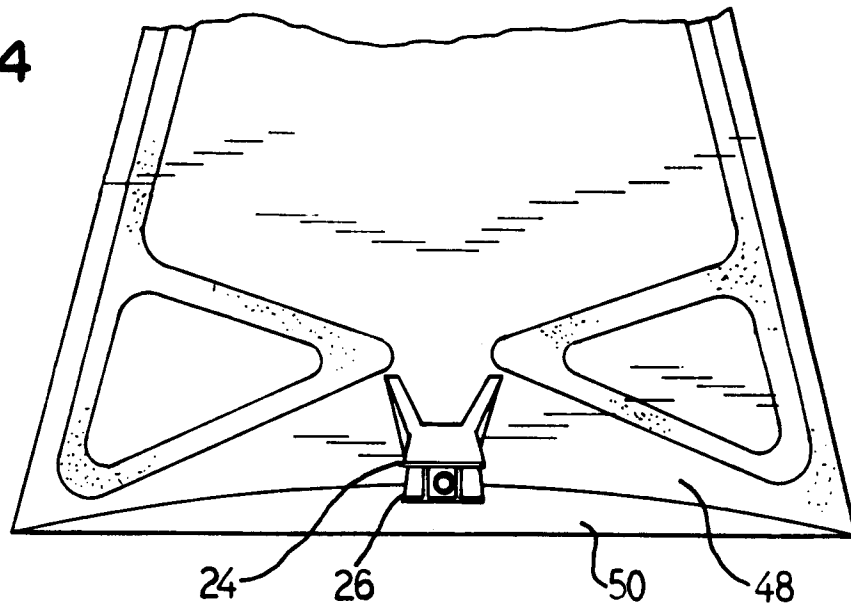


FIG. 5

