United States Patent [19]

Faust

[11] **3,898,023**

[45] **Aug. 5, 1975**

[54] **EXPANDABLE HOLDER APPARATUS FOR FLATTENING AND FREEZING FLUID-CONTAINING FLEXIBLE POUCHES**

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[73] Assignee: **Union Carbide Corporation**, New York, N.Y.

[22] Filed: **Sept. 23, 1974**

[21] Appl. No.: **508,720**

Related U.S. Application Data

[63] Continuation of Ser. No. 473,701, May 28, 1974, abandoned, which is a continuation of Ser. No. 337,332, March 2, 1973, abandoned.

[52] **U.S. Cl.** **425/110**; 425/177; 425/470; 62/341; 62/530; 53/127; 62/1; 62/62

[51] **Int. Cl.** **B29d 31/00**

[58] **Field of Search** ..... 425/110, 175, 177, 445, 425/425; 62/1, 60, 371, 530, 470; 53/124 A, 124 B, 127, 25

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Attorney, Agent, or Firm—M. W. Ryan

[57] **ABSTRACT**

Flat parallel plates are assembled onto a flexible pouch slack filled with fluid. The plates are lockably held but free to move expandably to a limited extent while maintaining interplate planar parallelism. The assembled plates holding the pouch are inserted into a plate retaining holder which bears yieldably against the plate outermost surfaces to accommodate the interplate planar parallel movement of the plates occasioned by subjecting the pouch and its contents while held in the assembled apparatus to rapid freezing in a cryogenic medium.

18 Claims, 8 Drawing Figures

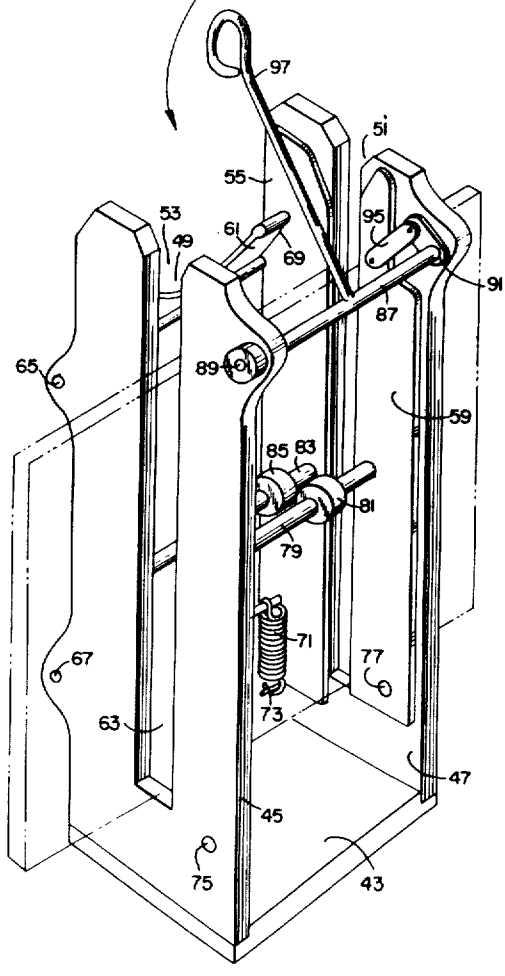


FIG. 1

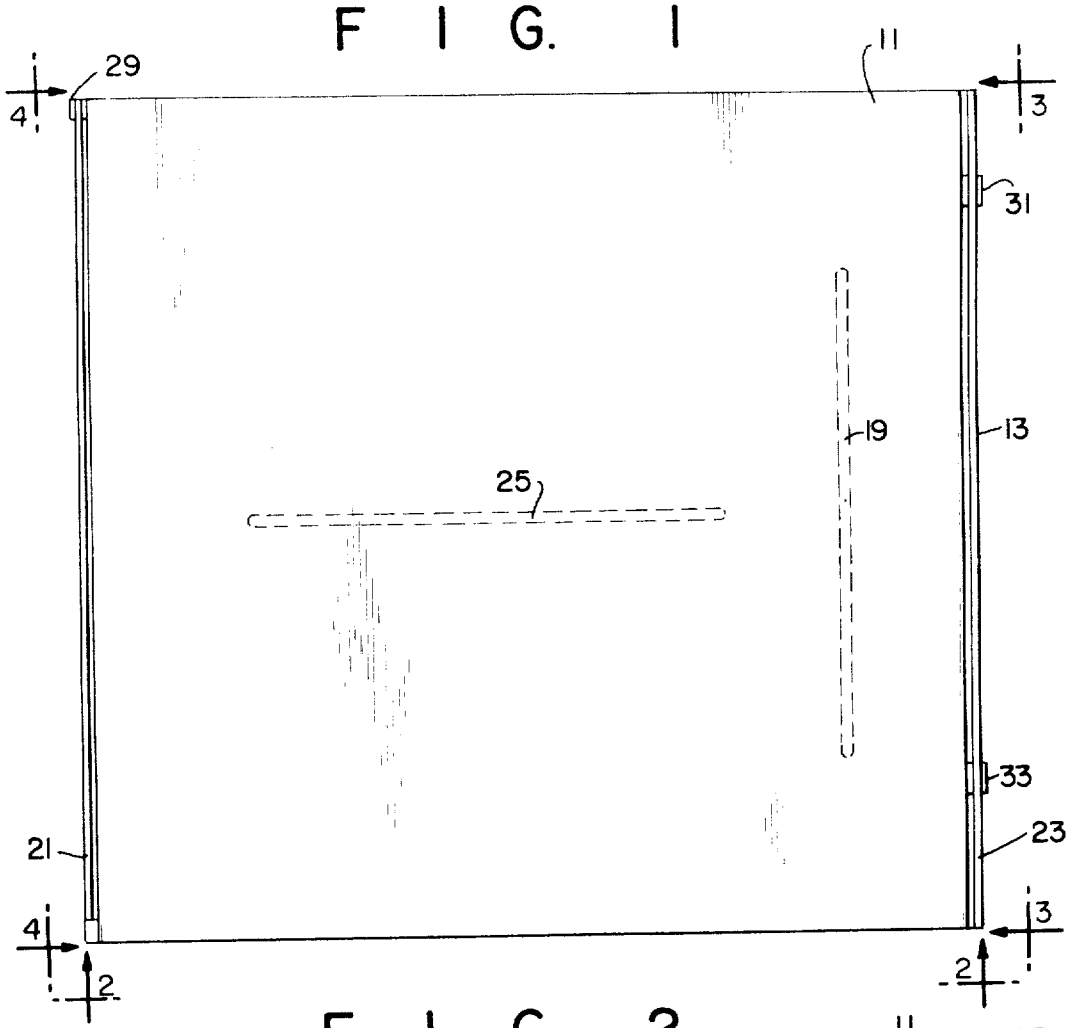


FIG. 2

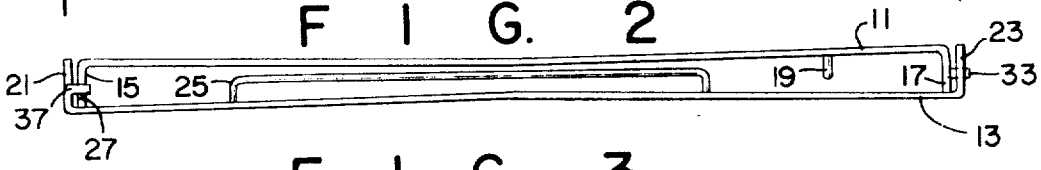


FIG. 3

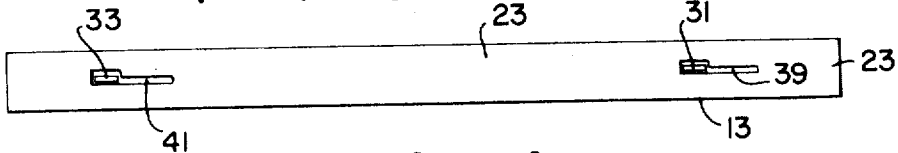
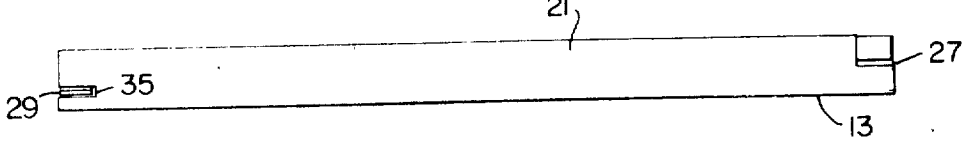


FIG. 4



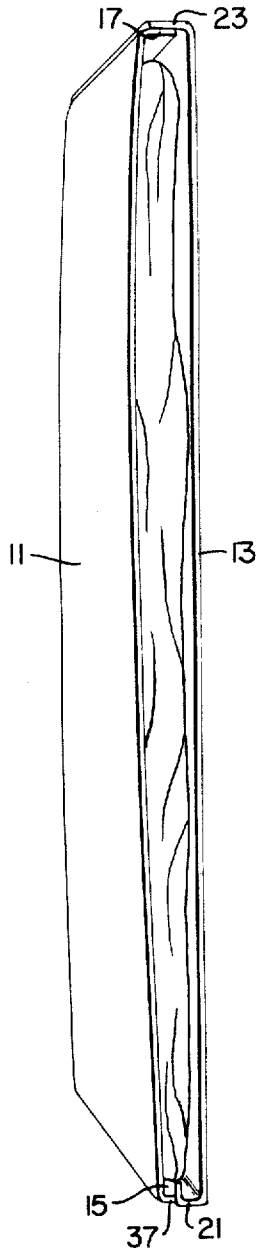

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FIG. 5

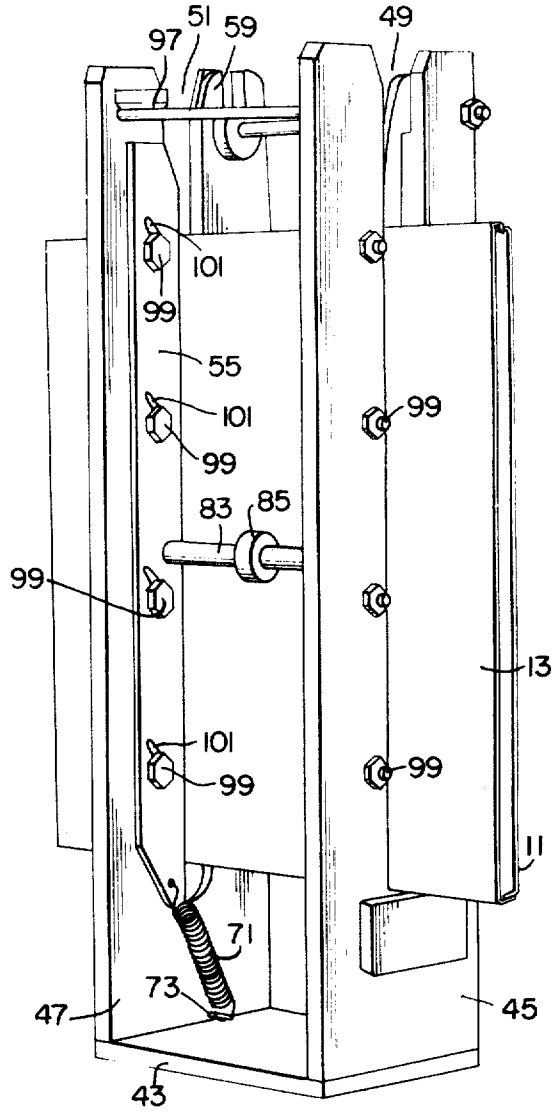

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FIG. 7

FIG. 6

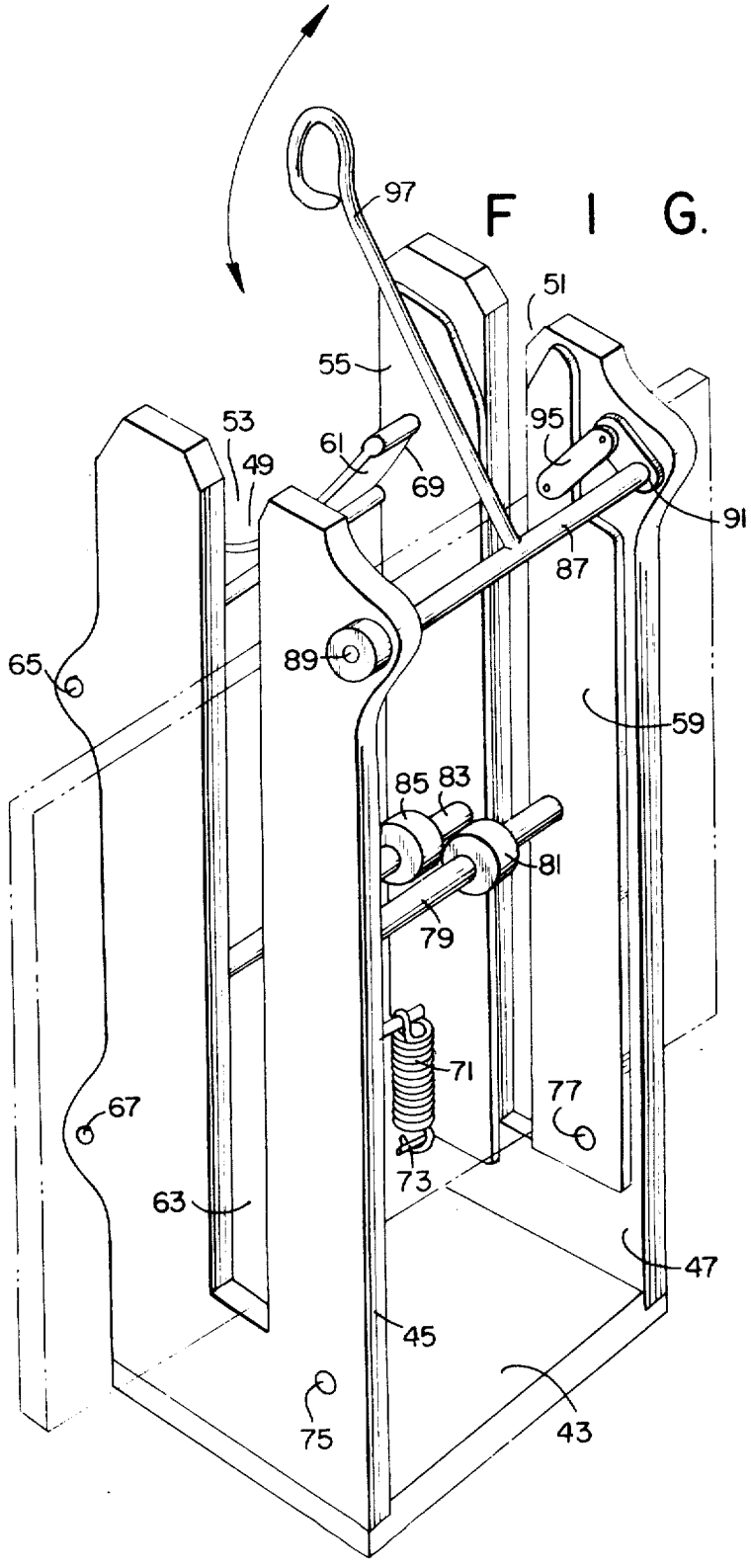
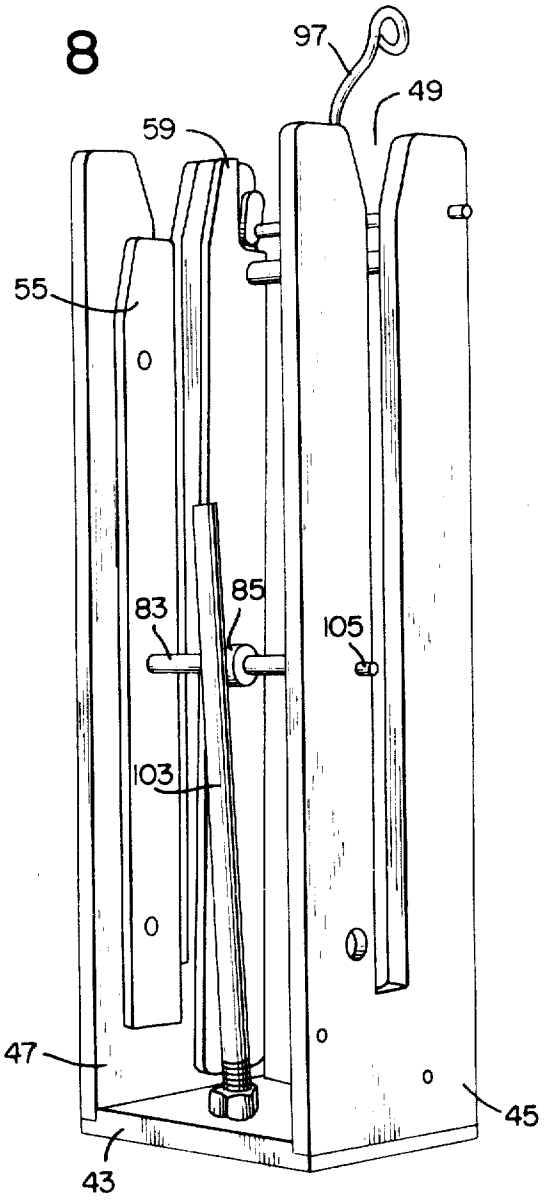

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FIG. 8



EXPANDABLE HOLDER APPARATUS FOR FLATTENING AND FREEZING FLUID-CONTAINING FLEXIBLE POUCHES

This is a continuation of application Ser. No. **473,701** filed May **28, 1974,** now abandoned, which is a continuation of application Ser. No. **337,332,** filed Mar. **2, 1973,** now abandoned.

This invention relates to apparatus for rapid freezing fluids into uniformly thin layer-like transportable and storable unitary packages handled at cryogenic temperatures in the order of about that of liquid nitrogen, −193°C. More particularly, the present invention relates to apparatus for the rapid freezing of flexible pouches slack filled with viable and perishable fluids, particularly biomedical fluids such as blood, blood platelets and other fluid components of blood, into thin layer-like package units which are easily handled and stored at cryogenic temperatures without suffering breakage, leakage, contamination or other damage.

The effective and efficient sterile packaging and preservation for future use of biological fluids such as fluid components of blood has long been and continues to be of great importance and interest in the biomedical arts. Significant progress has been made in this area using rapid freeze preservation techniques involving a variety of cryoprotective systems in conjunction with freeze-thaw-wash methods applied to such fluids in containers. Preservatives and/or cryoprotective agents such as glycerol and other additives may also be included in the containers with the fluid to be processed in quantities and manners within the ken of persons familiar with the art. This new technology makes possible hitherto unattainable desiderata such as the ready availability from freeze storage of blood platelets for leukemia patient treatments, rare blood type components which may now be effectively preserved and stored, red blood cells for treatment of oxygen deficiency cases and the facile handling of blood plasma. With regard to freezing operations on such fluids, the cellular components of blood in particular, it is important to maintain the fluid mass in as uniform a cross section as possible, mainly in order to attain the controllable rapid freeze and thaw rates essential to the prevention of rupture or other damage to the cells and also to produce a uniform product suitable for storage. It has been found that a relatively uniform flat thin cross section is particularly suitable and yields a high quality product with nicely controllable rapid freeze and thaw rates. These desirable relatively flat, thin, and uniform cross sections are obtained inherently with the use of flexible flat packages or pouches such as the pouches described and illustrated in U.S. Pat. No. **3,576,650** to Underwood.

A flexible pouch has a maximum fluid containing capability equal to the volume of the spherical form it will naturally assume when filled while unrestrained in any manner. Since the fluid containing volume of such a pouch however lessens considerably as the pouch shape changes from the spherical to the flat shape, it is necessary that the pouches in practicing this invention be slack filled, that is to say with a fluid volume not more than will insure maintenance of the desired thickness and shape when held flattened and restrained. In order to maintain this desired cross section and overall package configuration with such pouches during the freezing operation they must perforce be kept flattened

and an obvious way to do this is to freeze the fluid filled packages in a horizontal orientation. The freezing of horizontally oriented flat packaged fluids however has been found adversely to affect the rapidity and uniformity of freeze rates because when a fluid filled package and its support are immersed in the cryogenic medium, liquid nitrogen for instance, gas bubbles of the vaporized freezing medium form beneath the underside of the horizontally disposed assembly creating random insulative pockets which interfere with an even and rapid heat transfer from the product being frozen.

Efforts to obviate the problems attending rapid horizontal freezing of such fluids have led to the development and use of thin rigid stainless steel fluid containers which maintain the fluid cross section as desired independently of container position, can be immersed vertically in the freezing medium and make for very rapid freeze rates due to the good thermal conductivity of the metal. Such containers are also suitably durable and puncture resistant for handling, transport and storage. There are however numerous disadvantages to these metal containers. First and of great importance the necessity of venting a viable fluid metal container to the atmosphere during both filling and dispensing makes for difficulty in maintaining the sterility essential to the use of such product, particularly in effecting a sterile closure on the filled container. Since the metal is opaque, it is impossible to inspect the inside of the container for the possible presence of particulate foreign matter or other visible indicia of contamination, or to see the contained product itself. The container units are expensive to fabricate and are not reusable. Further, it is virtually impossible to apply any sort of kneading action when desired to effect mixing of the fluid product during the thaw process since the container metal walls cannot be kneaded in the manner of flexible plastic pouches.

Thus it can be seen that efforts to date in the art of cryogenic processing of viable and perishable fluids have solved one set of problems only to encounter others. Further efforts directed to improving either the horizontal or the vertical freezing techniques similarly have produced less than completely satisfactory results.

In the copending application of Faust et al, Ser. No. **176,214,** filed Aug. **30, 1971** and assigned to the same assignee as this application, there is described a method and apparatus for holding flexible pouches slack filled with fluids between a pair of substantially planar parallel flat plates and retaining the assembled plates and pouch in a jig fixture holder in a cryogenic medium while subjecting the whole array to cryogenic freezing. The invention of this copending application, it has been found, has made for a significant advance in the art. The present invention is considered to be an improvement on the invention of application Ser. No. **176,214** and its main feature and objectives are thus substantially similar to those of the aforesaid copending application.

Experience gained in practicing the invention of application Ser. No. **176,214** has indicated the desirability of some improvements in apparatus and has led to the conception and development of the present invention which has, in addition to the advantages and features of the earlier invention, greatly enhanced ability to produce thin flat frozen pouches by more reproducibly uniform freeze expansion control.

A further advantage of the invention is the provision of an improved easily applied and easily removed bag holder plate set, the two plate elements of which are completely separable and which, when assembled around a pouch slack filled with fluid, move easily and in a preselected mode to accommodate freeze expansion of the fluid.

The invention further provides improved apparatus means to hold the plate sets and pouches retained flatly therein for freezing operations, said apparatus means being adapted to apply yieldable restraint to the freezing expansion over plate outer areas not hitherto attainable and thus produce more uniformly flat finished frozen articles.

These and other objects of the invention will be the more readily appreciated and understood from the ensuing description and the drawings wherein;

FIG. 1 is a plan view of a pouch holder plate set according to the present invention;

FIG. 2 is an edge elevation of the plate set taken along lines 2—2 of FIG. 1;

FIG. 3 is an end elevation of the plate set taken along lines 3—3 of FIG. 1;

FIG. 4 is an end elevation of the plate set taken along lines 4—4 of FIG. 1;

FIG. 5 is a perspective view of a plate pair assembled on a pouch slack filled with fluid;

FIG. 6 is a perspective view of a plate retainer jig according to the present invention;

FIG. 7 is a perspective view of a plate retainer jig with an assembled plate pair in place therein, and

FIG. 8 is a perspective view of an alternative embodiment of plate retainer jig according to the invention.

In general, the present invention comprehends apparatus for holding a flexible pouch containing fluid in a condition and orientation for freezing into a thin layer-like unitary article and comprises, in combination, a pair of substantially flat parallel planar plates separable to permit enclosure of a slack filled pouch of fluid to be frozen, edge connecting means on at least two edges of the assembled plates pair arranged and disposed to hold said pouch flattened, said edge connecting means on at least one of said two edges being moveable in a direction which permits expansion of said pouch against the plate pair, a plate pair holding jig fixture, first plate bearing means mounted moveably on the jig fixture and arranged to bear yieldably on the outer surface of one of the plates of a pair plate disposed in the jig fixture, resilient means operably connected between the first plate bearing means and the jig fixture to effect yieldable bearing of said first plate bearing means on said outer surface of said one of said plates of said plate pair disposed in the jig fixture, second plate bearing means mounted moveably on the jig fixture, arranged to bear on the outer surface of the other of the plates of said plate pair disposed in the jig fixture when moved into a second position from a first position wherein said second plate bearing means is substantially out of bearing contact with said outer surface of said other of said plates of said plate pair, and means to move the second plate bearing means between and into said first and said second positions.

With reference to the drawings, FIGS. 1 through 4 show a pair of pouch holding plates 11, 13 which are separable to permit enclosure of a fluid containing pouch to be flattened and frozen. Plate 11 is formed with angular edges or returns 15, 17 and provided if desired with a bag stabilizing protuberance such as gripping rod 19. Plate 13 is also formed with returns 21, 23 and may also be provided with a gripping rod 25.

The return of plate 11 is provided with a notch 27 at one end and a key tab 29 at the other. Key tab 29 may be conveniently formed by cutting into the return 15 edge and bending the tab into a position normal to the return outer surface or face. The return 17 of plate 11 is provided with key tabs 31, 33 which extend from the return and which conveniently may also be formed by cutting into the return 17 edge and bending the tabs into respective positions normal to the return face as shown.

The return 21 of plate 13 is provided with a notch 35 at one end and a key tab 37 at the other. Key tab 37 may be conveniently formed by cutting into the return 21 edge and bending the tab into a position normal to the return inner surface or inside face. The return 23 of plate 13 is provided with L shaped slotted openings 39, 41 which are disposed and arranged to effect registration with the key tabs 31, 33 extending from return 17 of plate 11.

As shown in the drawing FIGS. 1 through 4, when the plate pair is assembled, the tab keys 31, 33 extending from return 17 of plate 11 engage the respective openings 39, 41 in the return 23 of plate 13 and are disposed in the widened portions of these openings, the key tab 29 extending from return 15 of plate 11 is engaged in notch 35 of return 21, and the key tab 37 extending inwardly from return 21 is engaged in notch 27 of return 15 of plate 11.

To assemble the plate pair around a pouch which has been slack filled with fluid to be frozen, the plates are separated from the positions shown in FIGS. 1 through 4 of the drawings by sliding plate 11 upward towards the top of the drawing sheet from its FIG. 1 position while holding plate 13 against movement. This moves the key tabs 31, 33 into the narrow portions of the openings 39, 41 and effects disengagement of key tab 29 from slot 35 and the key tab 37 from slot 27 so that the plate pair can be swung open and separated to disengage the key tabs 31, 33 from openings 39, 41. A slack filled pouch is laid into place on the plate 13 and plate 11 is reassembled thereto by reverse performance of the aforedescribed steps. The plate pair assembled and locked on a slack filled pouch is shown in FIG. 5 of the drawings.

FIG. 6 of the drawings shows a jig fixture according to the present invention for holding and clamping during freezing of the assembly shown in FIG. 5. As shown in FIG. 6, the jig fixture comprises a horizontal base 43 fixedly supporting oppositely disposed vertical sides 45, 47 to define a generally U configured rigid frame. Sides 45, 47 are formed to include slots 49, 51 respectively, which are aligned and of a slot width to accommodate the assembled pouch and plate set to be processed.

A first set of bearing rails 53, 55 is arranged between the sides 45, 47 on one side of the slots 49, 51 and a second set of bearing rails 57, 59 is arranged between the sides on the other side of the slots. The bearing rails 53, 55 are connected by laterally extending bearing rail connectors 61, 63 which mount pivotally to the sides as shown at 65, 67 and rigidly to the bearing rail inner surfaces as at 69. A spring 71 is tensionally connected between the lower connector 63 and a pin 73 extending from the inner face of side 47, resiliently pulling the bearing rail 53, 55 and connector 61, 63 assembly

downward and inward towards the slots about pivot points **65, 67** to effect a resiliently yieldable bearing contact of the bearing rails **53, 55** inner edges against a plate of a plate pair inserted into the slots.

The bearing rails **57, 59** are pivotally mounted to the jig sides **45, 47** at **75, 77** and secured together for uniform pivotal movement about the pivot points by a connecting rod **79** mounting at its midpoint a bearing disc **81**, the periphery of which aligns with the bearing rail **57, 59** inner edges so as to bear centrally on the plate it will abut. A similar and juxtaposed connecting rod **83** and disc **85** is advantageously provided connected to and extending between the first bearing rails **53, 55.**

Bearing rails **57, 59** are moved into and out of contact with a plate of an inserted plate set by means of an actuating assembly comprising a shaft **87** journalled in the sides **45, 47** as at **89, 91**, mounting bell crank linkages **93, 95** which connect operably to the rails as shown. An operating lever **97** is provided on shaft **87** and is used to effect movement of the bearing rails **57, 59** between and into a first position wherein there is no bearing contact urged against an inserted plate set and a second position wherein bearing contact is effected. The operating arrow in FIG. **6** indicates this operation with the swing towards the first position designated OPEN and the swing towards the second position designated CLOSE.

FIG. 7 of the drawings shows a modified embodiment of the apparatus with a plate set in place in the slots and the mechanism closed, that is to say ready for freezing, with the first bearing rail set in yieldable resilient bearing contact along two vertical loci on a plate **13**, and the second bearing rail set bearing on a plate **11** along two juxtaposed vertical loci. In the FIG. 7 embodiment, the bearing rails **53, 55** are not connected by bearing rail connectors such as **61, 63** but are instead slideably mounted to the sides **45, 47** by means of mounting bolts **99** and running slots **101** in the bearing rails. The embodiment illustrated in FIG. **7** also includes a different style of operating lever **97** and camming elements instead of bell crank assemblies to move the bearing rails **57, 59** into and out of bearing position.

Drawing FIG. **8** illustrates another alternative embodiment of jig fixture according to the invention wherein the first bearing rails **53, 55** are connectedly mounted between the sides by means of reduced diameter or turned down ends of shaft **83** which extend into slotted horizontal openings **105, 107** in the sides **45, 47.** In this embodiment of jig fixture, the bearing rails **53,** 55 are free to move pivotally about the shaft **83** ends and the resilient force to urge assembly into contact with a plate of an inserted plate set is provided by a cantilevered rod **103** installed as shown extending from the base **43** and exerting a load force on disc **85** of the first bearing rail assembly. A variation of the second bearing rail actuating mechanism is also shown in the FIG. **8** embodiment. As shown the camming action is in the closing or bearing direction only, the swing of the operating lever to the open or first position effecting only a release of the bearing pressure of bearing rails **57, 59** from the plate surface.

There are thus several if not many possible embodiments of the jig fixture used in the present invention it being only necessary that the plate set be held so that the bearing pressure against which freeze expansion applies is a yieldable bearing pressure and also necessary that some means is provided to load and unload the plate-held pouches with reasonable facility.

Other embodiments of pouch retaining plate sets are also possible. In the embodiments hereinafter described, the edge connecting means of the plates are such that both connected edges are moveable in the direction of thickness expansion of the freezing slack filled flattened pouch. This capability is readily obtained in the described embodiment as well as in possible alternative embodiments by the provision of enlarged or oversized slots and the like to accommodate registering elements such as key tabs and the like in a manner so as to permit movement of the pouch retaining plates outwardly from each other while maintaining interplate planar parallelism.

To operate the apparatus of the invention the jig fixture is customarily preinstalled in a cryogenic medium container which is filled with the freezing agent, liquid nitrogen for instance. A slack filled pouch is loaded into a plate pair as hereinbefore described and this assembly is inserted into the jig fixture slots **49, 51** with tongs or the like with the actuating mechanism of the second bearing rail set in the open position. The lever **97** is then swung to the close position with tongs or the like and left there until freezing is complete, at which time the lever is swung to the open position again and the plate-held pouch of frozen fluid removed from the jig and freezing medium.

While the apparatus of the invention has been described in connection with rapid freezing and freezing at cryogenic temperatures, it is to be understood that the invention is useable and useful as well in any heat transfer operations where the substances being processed undergo expansion.

Numerous alternative embodiments within the scope and spirit of this invention will, in the light of the foregoing description, undoubtedly occur to persons familiar with the art. The description is thus to be taken as illustrative only for the purpose of conveying an understanding of the invention and is not to be construed in any limiting sense.

What is claimed is:

1. Apparatus for holding a flexible pouch containing fluid in a condition and orientation for freezing into a thin layer-like unitary article comprising, in combination,

a pair of substantially flat parallel planar plates separable to permit enclosure of a slack filled pouch of fluid to be frozen,

edge connecting means on at least two edges of the assembled plates arranged and diposed to hold said pouch flattened, said edge connecting means on at least one of said two edges being moveable in a direction which permits expansion of said pouch against the plate pair,

a plate pair holding jig fixture,

first plate bearing means mounted moveably on the jig fixture and arranged to bear yieldably on the outer surface of one of the plates of a plate pair disposed in the jig fixture,

resilient means operably connected between the first plate bearing means and the jig fixture to effect yieldable bearing of said first plate bearing means on said outer surface of said one of said plates of said plate pair disposed in the jig fixture.

second plate bearing means mounted moveably on the jig fixture, arranged to bear on the outer sur-

face of the other of the plates of said plate pair disposed in the jig fixture when moved into a second position from a first position wherein said second plate bearing means is substantially out of bearing contact with said outer surface of said other of said plates of said plate pair, and

means to move the second plate bearing means into said second position.

2. Apparatus according to claim **1** wherein the first plate bearing means comprises a pair of bearing rails disposed to effect yieldable bearing pressure on a first plate of a plate set held in the jig fixture along two spaced apart parallel vertical loci.

3. Apparatus according to claim **2** wherein the second bearing means comprises a pair of bearing rails disposed to bear on the other plate of said plate set along two spaced apart vertical loci in substantial juxtapositioned to said loci on said first plate.

4. Apparatus according to claim **1** wherein said resilient means is a spring mechanism operably connected between said first plate bearing means and the jig fixture.

5. Apparatus according to claim **1** wherein said resilient means is a cantilevered spring member.

6. Apparatus according to claim **1** wherein said means to move the second plate bearing means into said second position, includes means to move said second plate bearing means into said first position from said second position.

7. Apparatus according to claim **1** wherein said means to move the second plate bearing means is a cam mechanism.

8. Apparatus according to claim **6** wherein said means to move the second plate bearing means is a cam mechanism.

9. Apparatus for holding a flexible pouch containing fluid for freezing into a thin layer-like article, which apparatus comprises, in combination, a pair of substantially flat parallel planar plates separable to permit enclosure of a slack filled pouch of fluid to be frozen, and edge connecting means on at least two edges of the assembled plates arranged and disposed to hold said pouch flattened, said edge connecting means on at least one of said two edges being moveable in a direction which permits expansion of said pouch against the plate pair.

10. Apparatus according to claim **9** wherein the edge connecting means on a second of said edges is moveable in a direction which permits expansion of said pouch against the plate pair.

11. A jig fixture for holding a flexible pouch holder having a pair of substantially flat parallel planar plates arranged to hold a flexible pouch flat between the plates during freezing of a fluid contained in the pouch comprising, in combination,

first plate bearing means mounted moveably on the jig fixture and arranged to bear yieldably on the outer surface of one of the plates of a flexible pouch holder disposed in the jig fixture,

resilient means operably connected between the first plate bearing means and the jig fixture to effect yieldable bearing of said first plate bearing means on said outer surface of said one of said plates of said flexible pouch holder disposed in the jig fixture,

second plate bearing means mounted moveably on the jig fixture, arranged to bear on the outer surface of the other of the plates of said flexible pouch holder disposed in the jig fixture when moved into a second position from a first position wherein said second plate bearing means is substantially out of bearing contact with said outer surface of said other of said plates of said flexible pouch holder, and

means to move the second plate bearing means into said second position.

12. Apparatus according to claim **11** wherein the first plate bearing means comprises a pair of bearing rails disposed to effect yieldable bearing pressure on a first plate of a flexible pouch holder held in the jig fixture along two spaced apart parallel vertical loci.

13. Apparatus according to claim **12** wherein the second bearing means comprises a pair of bearing rails disposed to bear on the other plate of said flexible pouch holder along two spaced apart vertical loci in substantial juxtaposition to said loci on said first plate.

14. Apparatus according to claim **11** wherein said resilient means is a spring mechanism operably connected between said first plate bearing means and the jig fixture.

15. Apparatus according to claim **11** wherein said resilient means is a cantilevered spring member.

16. Apparatus according to claim **11** wherein said means to move the second plate bearing means into said second position, includes means to move said second plate bearing means into said first position from said second position.

17. Apparatus according to claim **11** wherein said means to move the second plate bearing means is a cam mechanism.

18. Apparatus according to claim **16** wherein said means to move the second plate bearing means is a cam mechanism.

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