

[54] **ORGAN ENCLOSURE MANTLE**

[75] Inventor: **Stanley G. Dienst**, Birmingham, Mich.

[73] Assignee: **Extracorporeal Medical Specialties, Inc.**

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Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 91,247, Nov. 20, 1970, abandoned.

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[51] Int. Cl. F28f 7/00

[58] Field of Search.....195/1-7; 165/46; 62/306, 513; 128/400, 401

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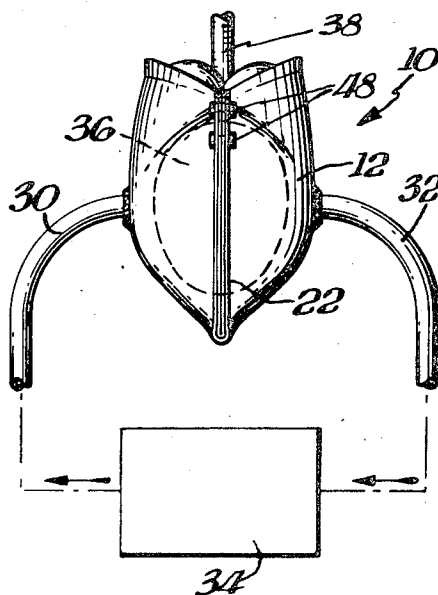
Primary Examiner—Charles J. Myhre
Assistant Examiner—Theophil W. Streule, Jr.
Attorney—Arthur G. Connolly et al.

[57]

ABSTRACT

An organ enclosure mantle comprises a flexible sac with a pocket-like membrane disposed therein and secured thereto along its top wall to form a closed chamber between the sac and membrane. The membrane includes an opening to permit an organ to be inserted therein. The membrane is made of a material which is expandable and heat exchangeable so that upon supplying a refrigerant to the chamber the membrane is caused to move into intimate contact with the organ and to maintain the organ at a cold temperature.

17 Claims, 13 Drawing Figures



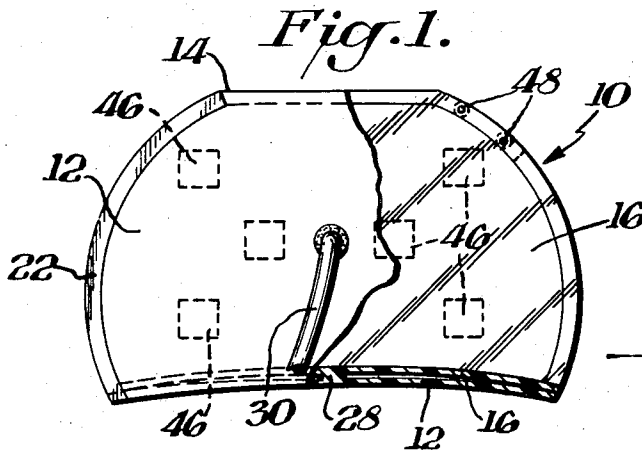


Fig. 6.

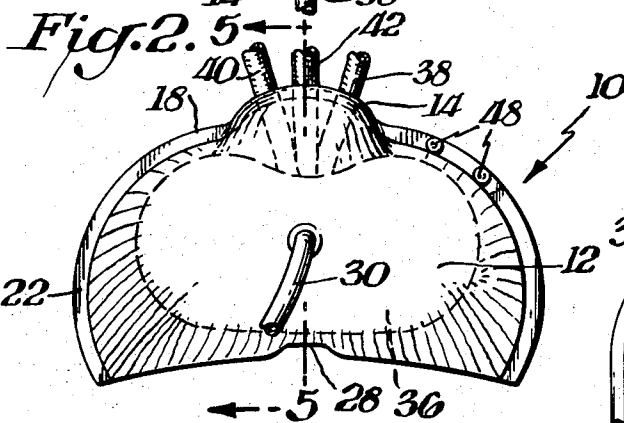
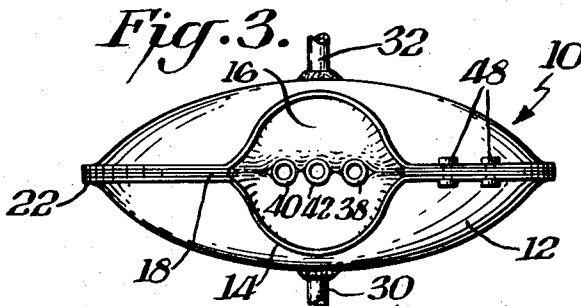
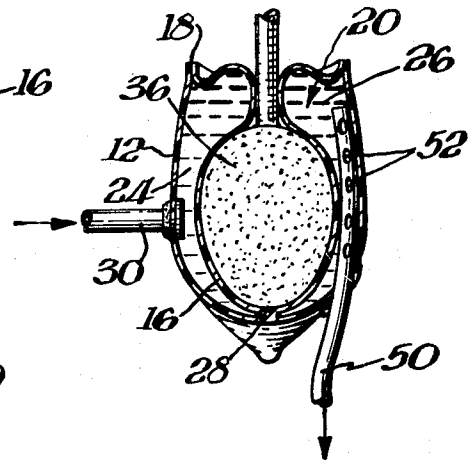


Fig. 4.

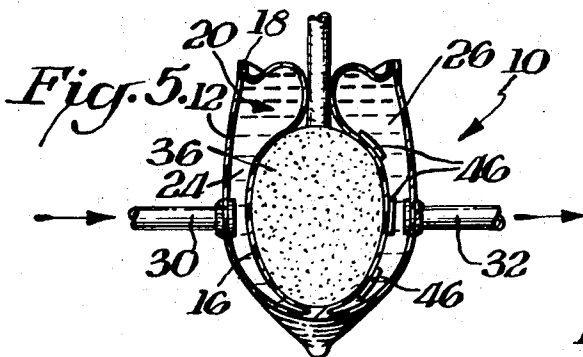
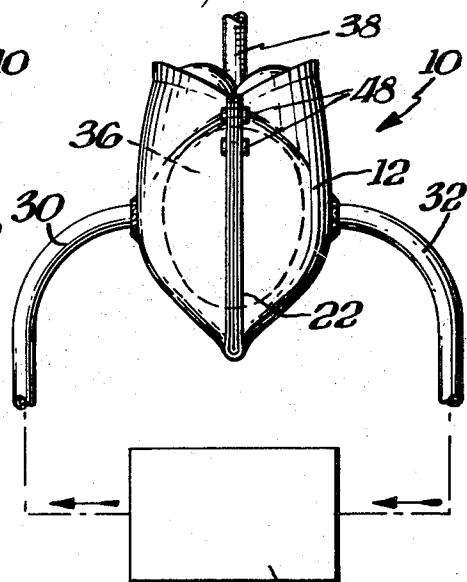
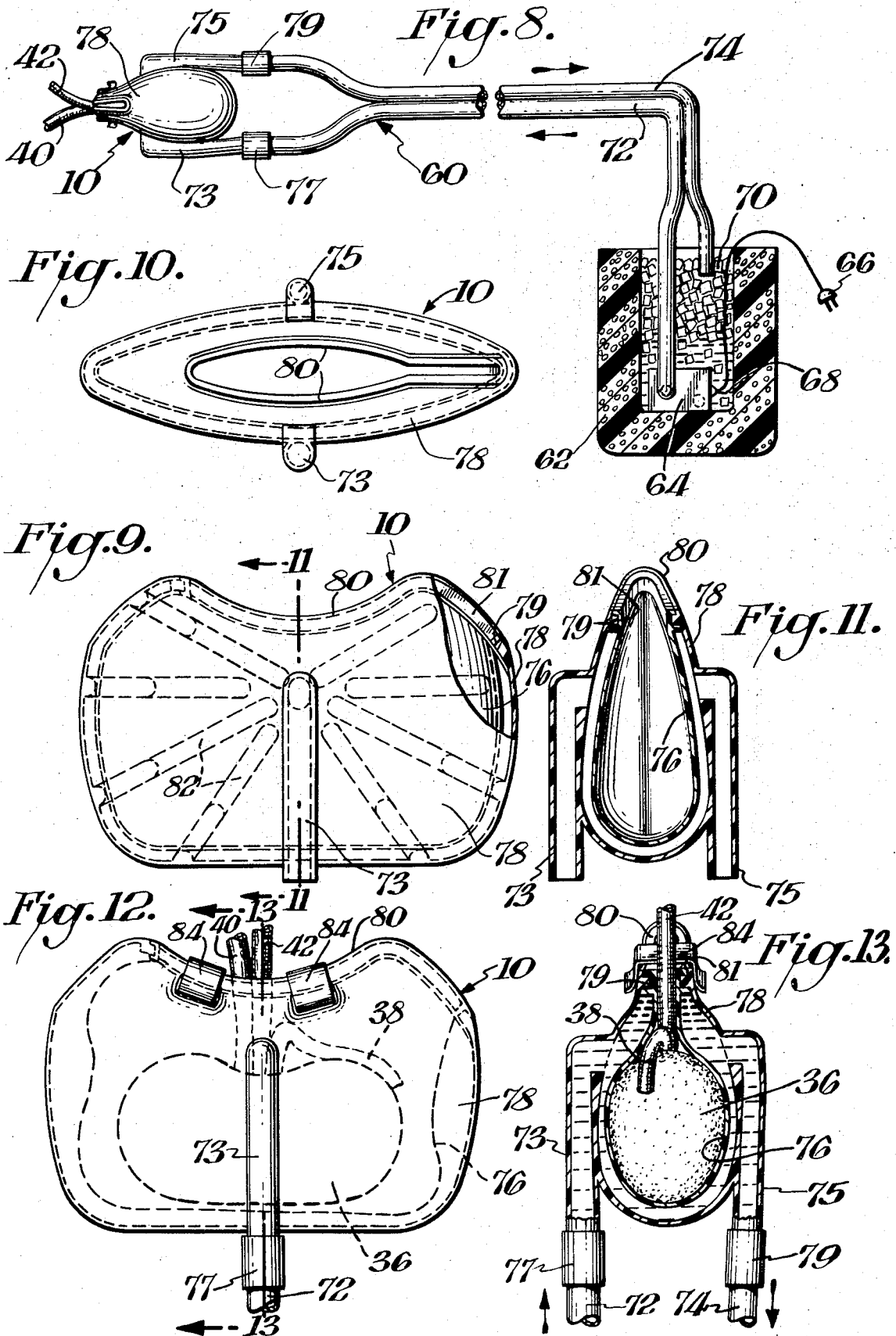


Fig. 7.





ORGAN ENCLOSURE MANTLE

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of my copending application Ser. No. 91,247, filed Nov. 20, 1970 now abandoned.

BACKGROUND OF INVENTION

This invention relates to an organ enclosure mantle and more particularly to such a mantle which is intended to be used in kidney transplant procedures.

The procedure of transplanting a kidney involves the surgical removal of a nondiseased kidney from a donor and the anastomosis of its artery and vein to major vessels in a recipient. This procedure necessarily requires the interruption of blood supply to the kidney for a period varying from 30 to 60 minutes. The most reliable and universally accepted method of preserving the potential function of a kidney during this period is cooling. Generally in such cooling procedures the kidney is immersed in a saline ice slush while cold electrolyte solution is perfused through the artery. This rapidly brings the core temperature of the kidney to 0° to 4°C. The kidney then may safely be left at this temperature for an hour or is often practiced even up to 6 hours. When removed from the ice bath, the kidney naturally starts warming. The outer cortical area of the kidney, which has the highest oxygen demand and is the most vulnerable to damage, is the exact portion which is warming most rapidly.

In experimental animals in a controlled laboratory situation where cooling is carried out immediately after interruption of the blood supply and the vessels are re-anastomosed in 20 minutes, urine output is immediate. The functions of glomerular filtration and tubular reabsorption are acutely reduced, but return to 80 to 90 percent of normal values within three weeks and eventually to greater than normal values (for one kidney).

In the clinical situation, however, the kidney has often been underperfused because of prolonged shock or even cessation of circulation in the donor. The vascular anastomosis takes longer, averaging 35 to 40 minutes. These liabilities in clinical transplantation are reflected in creatinine clearances (kidney function test) which often start at 20 to 30 percent of normal and rise over a period of months to 40 to 60 percent of normal, as well as blood urea levels, which remain abnormally high. These "average results" in the cadaver transplant indicate that the kidney has lost over 50 percent of its potential function. Often this is attributed to "rejection." However, the difference between the well preserved kidney and the one damaged by warm ischemia is often apparent before any rejection has occurred.

There is therefore a need for a mantle which effectively preserves the kidney and other organs by continuous cooling during anastomosis as required for successful transplants.

SUMMARY OF INVENTION

An object of this invention is to provide an organ enclosure mantle which effectively preserves an organ during transplanting procedures.

A further object of this invention is to provide such a mantle which is particularly useful in kidney transplant procedures.

In accordance with this invention an organ enclosure mantle comprises a flexible sac with a pocket-like membrane disposed therein and secured thereto along its top wall to form a closed chamber between the sac and membrane. The membrane includes an opening to permit an organ to be inserted therein. The membrane is made of a material which is expandable and heat exchangeable so that upon supplying a refrigerant to the chamber the membrane is caused to move into intimate contact with the organ and to maintain the organ at a cold temperature.

Spacers may be provided in the chamber to keep the walls of the sac and the membrane apart. If desired means may be provided at the common top wall of the sac and membrane to adjust the size of the membrane opening to accommodate different size organs. The sac and the membrane may be joined together at their side walls whereby the chamber is divided into an inlet side and an outlet side with the spacers being silicone rubber strips secured to the membrane in the outlet side of the chamber. The refrigerant supply means may be an inlet tube terminating at the side wall of the inlet side of the chamber, while an outlet tube may be provided on the outlet side of the chamber so as to permit the refrigerant to be circulated throughout the chamber. The outlet tube may have at least as great as or greater capacity than the inlet tube.

THE DRAWINGS

FIG. 1 is a side elevation view partly in section of an organ mantle in accordance with this invention in its non-use condition;

FIG. 2 is a side elevation view of the mantle shown in FIG. 1 during usage thereof;

FIG. 3 is a top plan view of the mantle shown in FIG. 2;

FIG. 4 is a side elevation view of the mantle shown in FIGS. 2-3;

FIG. 5 is a cross-sectional view taken through FIG. 2 along the line 5-5;

FIG. 6 is a cross-sectional view similar to FIG. 5 showing an alternative mantle;

FIG. 7 is an elevation view of a portion of a modified mantle similar to FIG. 1;

FIG. 8 shows the general arrangement for usage of the inventive mantle;

FIG. 9 is a side elevation view partly in section of a modified mantle in accordance with this invention;

FIG. 10 is a top plan view of the mantle shown in FIG. 9;

FIG. 11 is a cross-sectional view taken through FIG. 9 along the line 11-11;

FIG. 12 is an elevation view showing the mantle of FIGS. 9-11 in operation; and

FIG. 13 is a cross-sectional view taken through FIG. 12 along the line 13-13.

DETAILED DESCRIPTION

To minimize the warm ischemia, the kidney cooling jacket or mantle 10 has been developed to maintain the kidney at, for example, 4°C during the surgical vascular anastomosis. As shown in the drawings mantle 10 includes an outer sac 12 made of a flexible material and having an opening in its top wall 14. Disposed within sac 12 is a flexible pocket-like membrane 16 which is made of an expandable and heat exchangeable materi-

al. For example membrane 16 may be made of a thin gauge silicone rubber material, while sac 12 may be made of a thicker silicone rubber. This material is particularly suitable since it provokes no tissue reaction or toxicity and can be either gas sterilized or steam autoclaved. Top wall 14 is peripherally connected to membrane 16 as indicated by the seam 18 (FIGS. 5-6) to form a closed chamber 20 between the sac and membrane. Additionally, the side walls of the sac and membrane are connected together as indicated by the seam 22 so as to divide the chamber into inlet side 24 and an outlet side 26. The bottom wall is maintained open with spaced connecting points such as the single anchoring point 28 being provided between the sac and membrane to permit flow communication between inlet side 24 and outlet side 26.

An inlet tube 30 such as a silicone rubber tubing terminates at the side wall of sac 12 and communicates with inlet side 24 of chamber 20 while outlet tubing 32 is provided generally opposite thereto and also terminates at the side wall of sac 12 and communicates with the outlet side 26 of chamber 20.

During operation mantle 10 is inserted over the donor kidney and refrigerant is supplied to tubing 30 by any suitable means such as pump 34 (FIG. 4) into inlet side 24 of chamber 20. Outlet tubing 32 may be clamped to prevent flow therethrough so that the flowing refrigerant causes membrane 16 to move into intimate contact with the kidney. As shown for example in FIGS. 2 and 4 membrane 16 also bulges slightly outwardly so as to be in contact with the kidney vessels such as the ureter 38, the renal artery 40 and the renal vein 42. As shown in FIG. 7 the top wall 44 of mantle 10 is recessed or concave to facilitate approach to these kidney vessels. Once the membrane 16 is in intimate contact with kidney 36, the clamp is removed from outlet tubing 32 and refrigerant is circulated through mantle 10 with membrane 16 remaining in intimate contact with kidney 36. Since membrane 16 is made of a heat exchangeable material the temperature of kidney 36 is quickly brought down to the desired cooled temperature such as 0°-4°C. The refrigerant circulated through mantle 10 may be discharged from outlet tube 32 back to pump 34 or, if desired, to a separate receptacle.

For use with human kidneys the opening in the top wall of membrane 16 is about 2 - 2½ inches so that the kidney can be readily slipped into mantle 10. This part of the margin of mantle 10 can then be conveniently reopposed to contain the kidney by the application, for example, of a large curved Kelly clamp. A further advantageous feature of this invention is the provision of silicone rubber snap fasteners 48 to permit the size of the opening in the top wall of the mantle to be varied in accordance with the particular size kidney.

It has been found that in use with large human kidneys an intermittent ballooning effect occurs which is caused by the valve-like effect between the membrane wall and outlet tubing 32. In order to prevent this effect from occurring, membrane 16 is provided with a plurality of strips 46 of silicone rubber material on the outlet side 26 of chamber 20 to keep the walls of membrane 16 and sac 12 apart.

It is also advantageous that outlet tubing 32 have at least equal to or somewhat greater flow capacity than

inlet tubing 30. FIG. 6 shows another advantageous ramification wherein outlet tubing 50 is disposed within outlet side 26 of chamber 20 and contains a plurality of drain holes 52 to insure proper drainage of the refrigerant.

FIG. 8 shows the general operation of the mantle 10 wherein tubing means 60 is provided between the mantle and receptacle 62 for permitting communication between the mantle and submersible pump 64. Pump 64 includes suitable means 66 for connection to a power source. Receptacle 62 contains a saline solution 68 and chipped ice 70 to provide the necessary cold solution which is supplied to mantle 10 through tube 72 with the circulation being completed through tube 74 of tubing 60. Advantageously tubing 60 is in the form of double lumen tubing which is joined together between the pump 64 and mantle 10 and then separated at the mantle and near the pump.

FIGS. 9-11 show a modified form of this invention wherein the inner membrane 76 and the other sac 78 are integrally secured together at top wall 80 by being molded to shape thereby eliminating seams. Such an integral arrangement may be created by inserting the membrane in the sac and bonding the top edges of the membrane to the sac with a suitable adhesive or other suitable means. As shown, for example, in FIG. 11 tongue 79 of membrane 76 snaps into groove 81 of sac 78 and the tongue is held therein by suitable adhesive means.

As also shown in FIGS. 8 and 11 sac 78 includes integral tubes 73 and 75. Tube 73 is joined to tube 72 by suitable connector 77 while connector 79 joins tube 75 to tube 74. As is also apparent from FIG. 11 inlet tube 73 is of larger diameter and flow capacity than outlet tube 75.

FIG. 9 also illustrates another advantageous feature of this invention wherein the flexible membrane 76 and sac 78 are reinforced with suitable material such as dacron cloth 82 embedded in the silicone rubber and preferably in the wall of outer sac 78 thus allowing flexibility without distensibility.

A further advantageous feature is best illustrated in FIGS. 12-13 wherein the opening in the top wall is adjusted or controlled by the provision of U-shaped clips 84 made for example of stainless steel. After the kidney is inserted the clips would close the mantle by being placed on either side of the vessels to approximate the edges thereof.

Mantle 10 effectively provides a thin layer of cold solution between the cold hypothermic kidney and the ambient temperature around it. This ambient temperature may for example be between 25° to 37°C in the recipient operative wound. The cold barrier in chamber 20 prevents absorption of heat by the kidney and keeps the kidney at a temperature where function is known to be best preserved. Moreover, the shape of mantle 10 is made to conform closely to the kidney so that minimal room is occupied in the operative field to thereby minimize encumbrance to the surgeon.

The preferred material for the various components of mantle 10 is silicone rubber and the preferred refrigerant is cold water. Of course, however, other suitable materials or refrigerants may also be used within the concepts of this invention. Similarly, the mantle may be used for animal as well as human kid-

neys. Mantle 10 may in fact by proper alteration of shape be used as an enclosure for organs other than kidneys.

What is claimed is:

1. An organ enclosure mantle comprising a flexible sac having an opening in its top wall, a flexible pocket-like membrane disposed within said sac, said sac being secured to said membrane at said opening in its top wall to create a closed chamber between said sac and said membrane, said membrane having an opening in its top wall to permit an organ to be inserted therein, said membrane being made of an expandable and heat exchangeable material, and refrigerant supplying means communicating with said chamber for moving said membrane into intimate contact with the organ and for maintaining the organ at a cold temperature.
2. A mantle as set forth in claim 1 including refrigerant discharge means communicating with said chamber whereby refrigerant may be circulated therein.
3. A mantle as set forth in claim 2 including spacer means in said chamber for preventing complete surface to surface contact of said sac and said membrane.
4. A mantle as set forth in claim 3 including means for adjusting the size of said opening in said top wall of said membrane to accommodate different size organs.
5. A mantle as set forth in claim 4 wherein said adjusting means includes at least one V-shaped clip.
6. A mantle as set forth in claim 4 wherein said sac is generally kidney shaped.
7. A mantle as set forth in claim 6 wherein said sac and said membrane include side walls peripherally connected together and bottom walls connected together at spaced locations thereof.
8. A mantle as set forth in claim 7 wherein said chamber is divided by said side walls into an inlet side and an outlet side, said supplying means being on said inlet side of said chamber, said discharge means being on said outlet side of said chamber, and said spacer means being in said outlet side of said chamber.

9. A mantle as set forth in claim 8 wherein said discharge means includes a discharge tube projecting into said outlet side of said chamber, and a plurality of drain holes in said discharge tube.

10. A mantle as set forth in claim 8 wherein said membrane is made of thin silicone rubber material, said sac being made of thicker silicone rubber material, and said spacer means being strips of silicone rubber material secured to said membrane.

11. A mantle as set forth in claim 10 wherein said means for adjusting the size of said opening is a plurality of silicone rubber snap fasteners on the common top wall of said sac and said membrane, and said top wall being concave.

12. A mantle as set forth in claim 11 wherein discharge means is a discharge tube terminating at the side wall of said outlet side of said chamber and communicating with said chamber, said supplying means being a supply tube at the side wall of said inlet side of said chamber and communicating with said chamber, and said supply tube having a flow capacity no greater than the flow capacity of said discharge tube.

13. A mantle as set forth in claim 1 wherein said sac and said membrane are integrally secured together at said top wall in a seamless manner.

14. A mantle as set forth in claim 1 wherein said refrigerant supplying means includes a pump and tubing means connecting said pump to said chamber, and said tubing means being a pair of tubes joined together between said pump and said chamber and separated at said pump and said chamber.

15. A mantle as set forth in claim 1 wherein said sac and said membrane are adhesively bonded together at said top wall.

16. A mantle as set forth in claim 1 wherein reinforcing means are provided for said chamber.

17. A mantle as set forth in claim 16 wherein said reinforcing means comprises dacron cloth strips imbedded in the wall of said sac to provide flexibility without distensibility.

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