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Snowdon et al.

[11] **3,712,298**

[45] **Jan. 23, 1973**

[54] **MEDICAL TREATMENT APPARATUS**

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[73] Assignee: **National Research Development Corporation,** London, England.

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[21] Appl. No.: **66,767**

[52] **U.S. Cl.** **128/40,** 128/184, 128/299

[51] **Int. Cl.** **A61h 1/00**

[58] **Field of Search**...................128/1 A, 1 B, 38–40, 128/184, 256, 298, 299, 82.1

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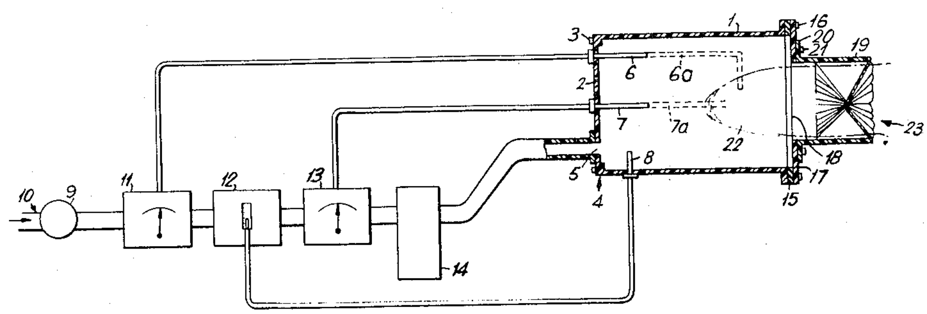
[57] **ABSTRACT**

Apparatus and method for treating a human limb. The apparatus comprises a container connected to a source of gas under pressure. The limb intrudes into the container through a seal which allows gas to leak out over the surface of the limb at a controlled rate, so ventilating the limb. The leaking seal is so constructed that it applies no tourniquet effect to the distal end of the limb within the container. The seal may register with a substantial length of the limb, which may thus be subjected to a beneficial pressure gradient.

6 Claims, 12 Drawing Figures



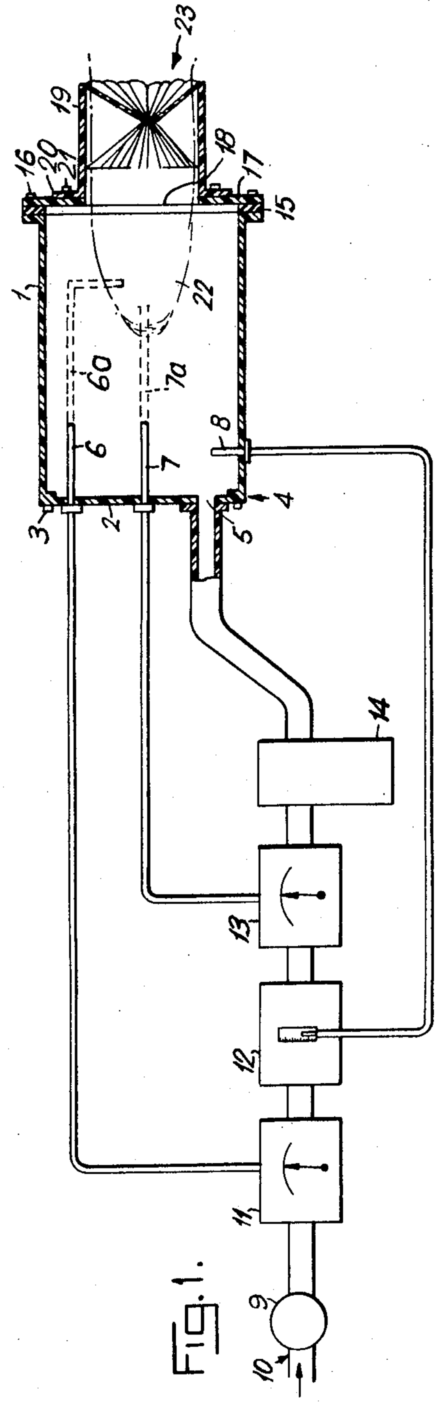

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Fig.1.

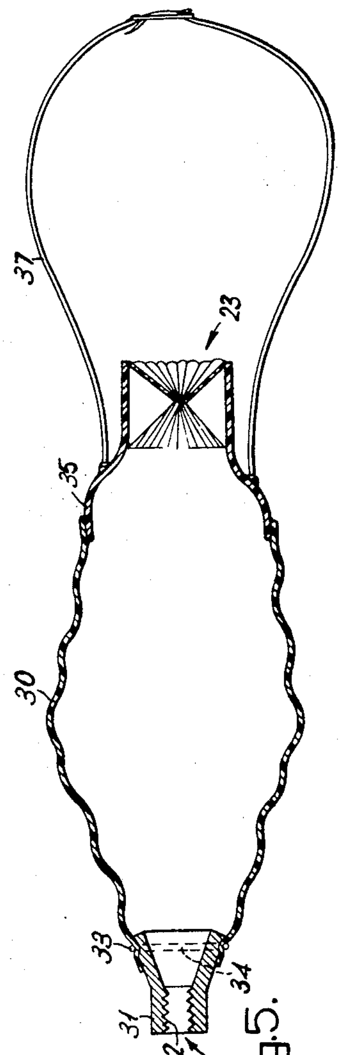
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Fig.5.

Fig.2.

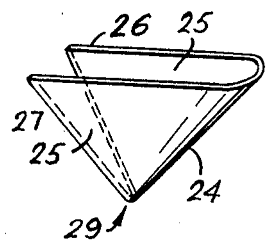


Fig.3.

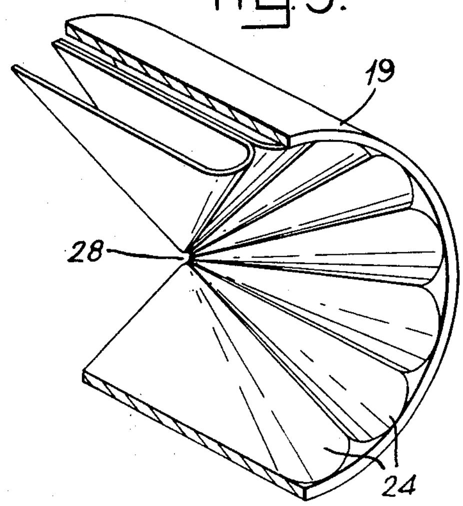


Fig.4.

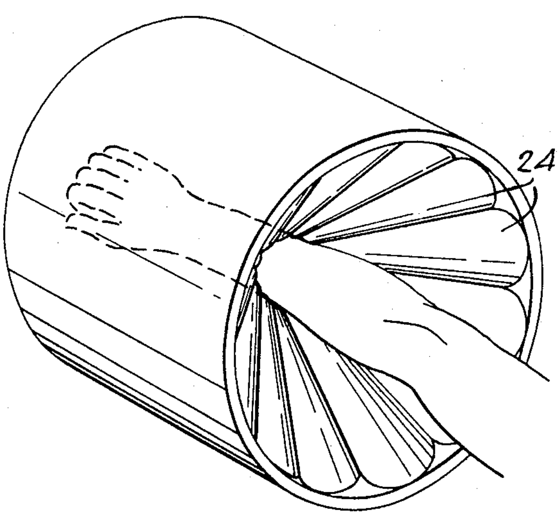


Fig.6.

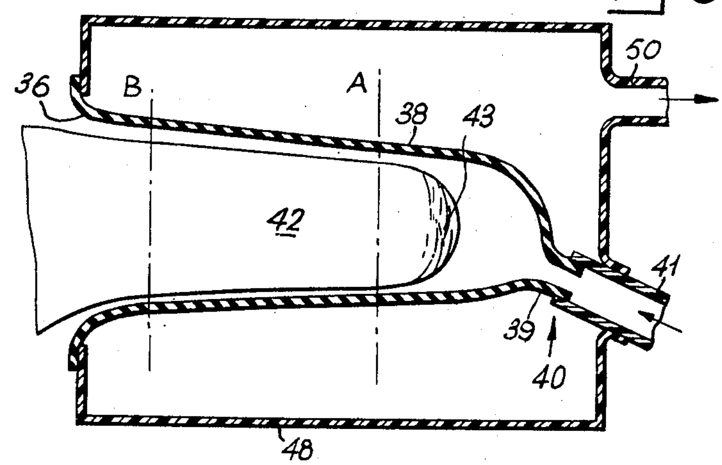


Fig.7.

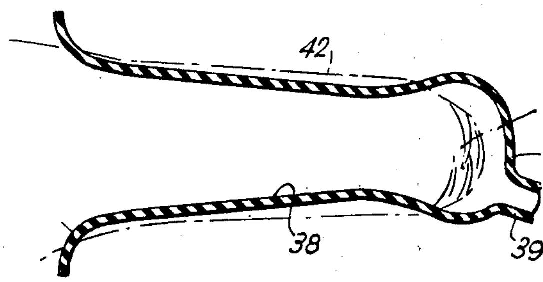
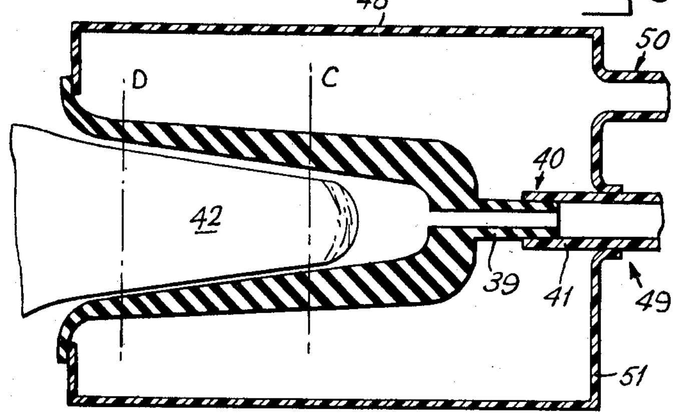


Fig.8.



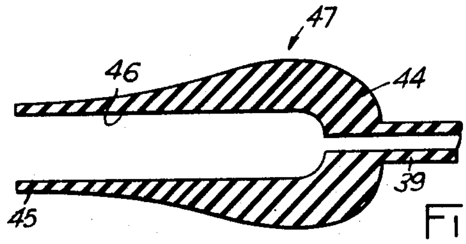


Fig.9.

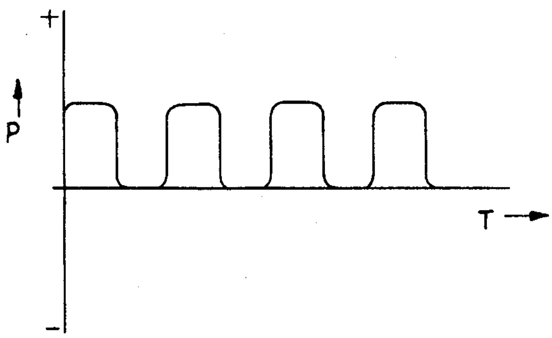


Fig.10.

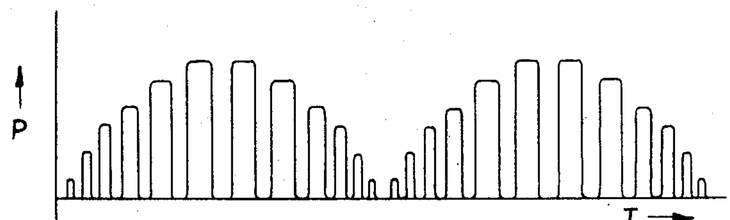


Fig.11.

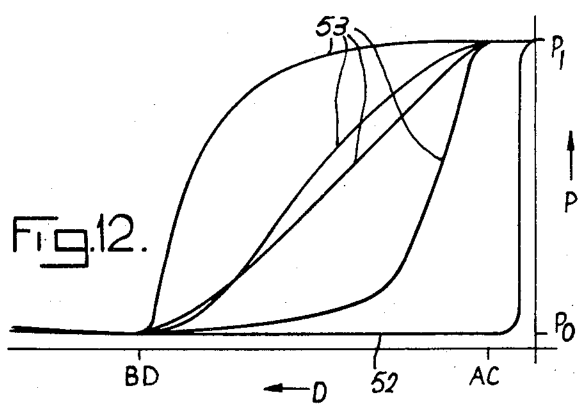


Fig.12.

MEDICAL TREATMENT APPARATUS

This invention relates to medical treatment of limbs of the body, and to apparatus for carrying out the treatment. It applies particularly to the treatment of limbs that have been badly burned, or of a limb such as the stump that remains after an amputation. During conventional post-operative treatment, such stump is encased in a fixed volume dressing such as a plaster cast. This treatment is beneficial because it opposes the tendency for fluids to accumulate and cause swelling. However, the treatment also has some disadvantages. For instance, slight movement of the stump within the cast may create a slight clearance between the distal end of the cast and the stump within it. This causes the maintained pressure between the rest of the cast and the stump to produce an undesirable tourniquet effect. The stump can also suffer from lack of ventilation and from other factors leading to sepsis, and the presence of the cast hinders any normal and regular examination whereby such a condition might otherwise be detected at an early stage. An object of the present invention is to facilitate medical treatment whereby these disadvantages may be diminished while many benefits are retained.

The scope of my invention is defined by the claims at the end of this specification, and certain apparatus according to the invention will now be described, with reference to the accompanying drawings, in which:

FIG. **1** is a part schematic drawing of one apparatus;

FIGS. **2**, **3** and **4** are perspective drawings of a detail of FIG. **1**;

FIG. **5** is an axial section through another apparatus;

FIG. **6** is a similar section through a further apparatus;

FIG. **7** is a diagrammatic drawing illustrating the form of the sock shown in FIG. **6**;

FIG. **8** is an axial section through yet a further apparatus;

FIG. **9** is an axial section through the sock of FIG. **7**, when not under pressure; and

FIGS. **10**, **11** and **12** are graphs illustrating modes of treatment possible with apparatus according to the invention.

In FIG. **1** treatment apparatus includes a container comprising a rigid transparent cylinder **1** of "Perspex" or similar material. At one end of the cylinder a rigid end plate **2** is fixed by bolts **3**, making a joint with the aid of a gasket **4**. End plate **2** contains an inlet **5** for air under pressure, and provides a mounting for a temperature sensor **6** and a humidity sensor **7**. A pressure sensor **8** is mounted in the wall of cylinder **1**. A pump **9** draws in fresh air or other suitable gas through an inlet **10** and pumps it first through a pressure regulating device **11** responsive to sensor **8**, then through a temperature regulator **12** responsive to sensor **6**, then through a humidity regulator **13** responsive to sensor **7**, and finally through a bacterial filter **14** before the air supply, now purified and carefully controlled as to temperature, pressure and humidity, enters the cylinder via inlet **5**. Regulating devices **11**, **12** and **13** may be preset. Alternatively, by means of a programming device, they may be programmed to maintain a desired relationship between the parameters concerned although the values of each of these may change. As indicated by the dotted extensions ***6a*** and ***7a*** of **6** and **7**, these sensors and others not shown could respond to conditions — e.g., surface temperature, weight, surface moisture, color, body temperature, etc. — on or in the limb itself, not just within the container.

At the other end of cylinder **1** a gasket **15** and bolts **16** make an air-tight joint with an end plate **17** containing a central aperture **18**. A hollow cylindrical member **19** carries a flange **20** which is fastened to the outer face of end plate **17**, around the aperture **18**, by bolts **21**. A human limb **22**, for treatment within chamber **1**, is inserted through cylindrical member **19**, at the righthand end of which is a seal **23**, described in more detail with reference to FIGS. **2**, **3** and **4**.

Inside chamber **1**, the limb may be subjected to sterile air under variable pressure, as will be described. It is essential, however, that the atmosphere should be capable of exerting a pressure upon the limb that exceeds atmospheric pressure, typically by 0.3 to 1.5 psi. It is also desirable that the seal **23** shall exert no greater pressure upon the part of the limb that lies within it than is exerted upon the rest of the limb lying within the chamber. Any "tourniquet" effect of the seal would be most undesirable. An element of a suitable seal, as used in the apparatus of FIGS. **1** and **5**, is shown in FIG. **2** and comprises a piece of flexible material, inelastic and preferably fluid-tight, folded at **24** to form a sling-shaped member with triangular sides **25** and U-shaped edges **26**, **27**. As FIG. **3** shows most plainly, the members are mounted in a ring around the inner surface of the free end of cylindrical member **19**, with sides **25** of adjacent members in contact and with edges **26** bonded to member **19** and lying parallel to the axis of it. The convex faces of the U-bends **24** face axially outwards, and the radial depth of the members is such that they leave a circular clearance **28** around the axis of member **19**. The girth of this clearance is smaller than that of any limb that may require treatment within the apparatus. When no limb is inserted through the seal, air at high pressure within cylinder **1** will cause each of the members of the seal to take up the shape shown in FIG. **3**, and throughput of air will be great because it can escape with ease through clearance **28**. However, when a limb is inserted, as shown in FIG. **4**, the radially inner end **29** of each U-bend **24** will conform to the surface of the limb, and air will escape through the seal by forcing itself through the gaps between the sides **25** of adjacent seal members, or by leaking through the similar clearance between the inner ends **29** of the seal members and the intruding limb. Thus the folds **24** of the seal members constitute a deflectable end wall of the container. When deflected by an intruding limb, the seal members take up a funnel shape in which the spout of the funnel is defined by the radially inner ends **29** of all the members, and the stem of the funnel is formed by the parts of the members that conform to the surface of the limb.

The flexibility of the material ensures that the pressure it exerts upon that part of the limb passing through the seal is dictated only by the pressure difference between the inside and outside of chamber **1**, and is nominally the same as that exerted upon all parts of the limb that lie completely within the chamber. Furthermore, the seal allows air to escape from within the chamber at a reasonable rate when a limb is inserted, and this facilitates continuous changing of the pressurized atmosphere within the chamber, and thus ventilation of the limb being treated, and prevents the ingress of undesirable bacteria.

Apparatus according to the invention enables pressure to be applied to the limb under treatment. The application of pressure is of benefit in counteracting oedema or swelling which endangers limbs so often after serious tissue damage such as amputation. Unlike the plaster cast, the apparatus shown in FIG. **1** allows the limb to be surrounded by an atmosphere of sterile air, to be ventilated by constant changing of that atmosphere, and to be continuously visible. The nature of the seal **23** is such that even if the girth of the part of the limb lying within it changes, the flexible material of the members of the seal will allow the dimensions of the seal to change with it without introducing extraneous pressures.

The apparatus so far described with reference to FIG. **1** has a rigid chamber and considerably limits the mobility of the patient. However, with the modified apparatus of FIG. **5** the patient can be a little more mobile. Here the wall **30** of the container is of lightweight, flexible, inelastic air-tight transparent plastics material, for example that sold under the trade mark "Melinex." The air inlet **5**, at the left-hand end in the figure, comprises a hollow conical boss **31** containing a threaded portion **32** to receive a hose carrying the pressure air supply. The flexible wall **30** is attached to boss **31** by a rubber ring **33** which registers with a groove **34**. At the other end, the wall **30** is bonded to a flexible sleeve **35** on which is mounted the seal **23**. A strap-type harness **37** is anchored to sleeve **35** at opposite ends of a diameter. This is necessary to attach the apparatus to the patient, since the higher pressure inside the chamber than outside tends to blow the apparatus off the patient. The same applies to the apparatus of FIG. **1**, but in that case the patient is almost bound to be a lying case and it will be simple to mount supports on the bed to prevent patient and apparatus blowing apart. With the apparatus of FIG. **5**, the harness **37** will pass round some part of the patient's body; for instance, if the limb being treated is the stump of an amputated leg, harness **37** may pass round the back of the patient's waist, or may be a form of shoulder harness.

The apparatus hitherto described enables the limb to be subjected to a uniform pressure, but not to a pressure gradient along the length of the limb. It may be desirable to subject a stump or other limb to such a pressure gradient, the maximum pressure being at the distal end of the stump, thus assisting the driving of fluid away from it towards the body. Apparatus according to the invention, which achieves this effect, is shown in FIGS. **6** to **8**. In FIG. **6** the container is a resilient, gas-tight sock **38** with a gas inlet **39** connected at **40** to a hose **41** coming from a pump, which may be associated with sensing and controlling devices as described with relation to FIG. **1**. **42** represents the stump of a human limb lying within the sock.

FIG. **7** compares the shape of a typical stump **42** with the shape of the sock **38** when unstretched. It will be seen that the sock is nearly as wide as the stump at the body end, then becomes progressively less than the stump in circumference until it approaches the area of the wound **43** at the tip of the stump, when it widens out again. If such a sock is fitted over such a stump, it will clearly fit loosely over the wound, will then tighten so as to become a "gaiter" around the limb. This gaiter grips most tightly shortly behind the wound, and grips progressively less tightly between that point and the proximal end of the sock. If the inlet **39** is now connected, as in FIG. **6**, to a source of gas under pressure, the end **44** of the sock that surrounds the wound will distend so that it lies clear of the wound, so that the wound receives the full pressure of the sterile air. Immediately behind the wound the pressure exerted by sock upon a stump is greatest, because, as FIG. **7** shows, the difference in diameter between the stump and the unstretched sock is greatest in the region. However, this region like the wound is subject to the full delivery pressure of the sterile air, which is set high enough to just separate sock and stump, creating the beginning of an annular-section passage for the flow of sterile gas between stump and sock. As the gas travels towards the remote end of the stump, the pressure of sock on stump progressively decreases but so does the pressure head behind the flow of air, due to the resistance that has already been overcome. In consequence, a clearance between stump and sock is maintained and the air flowing through this clearance subjects the stump to a pressure gradient. In effect, 'A' and 'B' in FIG. **6** mark the limits of the region in which the sock acts as a gaiter on the intruding limb, subjecting it to a pressure gradient. The leaking seal between sock and stump over this distance is comparable to that which existed between the intruding limb and the "stem" of the funnel shape formed by the members of the seal **23** in FIGS. **1**, **4** and **5**. This region of sock **38**, and the remaining part **36** of the sock to the left-hand side of line 'A,' together constitute the part of the wall of the container that deflects so as to yield to the intrusion of a limb.

FIGS. **8** and **9** illustrate a different construction of sock. This modification is shown in the unstretched state in FIG. **9** and is of resilient gas-tight material thicker at the distal end **44** than at the proximal end **45**, and having a bore **46** appropriate to stump circumference. As with the previous form of the invention, there is an inlet **39** at the distal end. When stump **42** is inserted, as in FIG. **8**, the greater thickness of the walls at the inner end give rise to a clearance between stump and sock between the limits C and D, just as the shape of the alternative sock did in FIG. **6** and **7**.

In FIG. **6**, **8** and **9** the containers constituted by socks **38** and **47** are surrounded by non-collapsible jackets **48** which have two inlets **49**, **50** in their end walls **51**. Inlet **49** is to receive pressure hose **41** for connection to inlet **39** of the sock. Inlet **50** is for connection to a vacuum source, not shown. When this source is energized, the parts of resilient socks **38** or **47** that act as gaiters to the limbs within are lifted quite clear of stump **42** so that the pressure at the surface of the stump is reduced to atmospheric level.

By cyclically applying a vacuum and atmospheric pressure at inlet **50** the stump **42** within socks **38** or **47** is subjected alternatively to atmospheric pressure and to a higher pressure. This cyclic variation in pressure has a desirable vascular pumping action; the intermittent higher pressure can tend to expel undesirable tissue fluids.

The pulsations just described with relation to the forms of the apparatus shown in FIGS. **6** to **9** can of course be applied to other forms of the invention. It can be effected in the forms shown in FIGS. **1** and **5** by simply using the pressure controller **12**, responsive to the sensor **6**, to produce a desired pattern of pressure changes within the container. FIG. **10** is a graph of pressure P against time T and illustrates a simple regular program of alternate pulses of equal length of uniform pressure and zero. FIG. **11** illustrates a more complicated pattern of pulses in which a succession of pulses of low pressure gives way gradually to a period in which the pulses are of higher pressure but are less frequent, and then proceeds in reverse sequence to conclude one cycle of a pressure pattern. FIG. **12** is a graph of pressure P against distance D and illustrates the pressure gradients that may be created by the gaiter parts of socks **38**, **47** in FIGS. **6**, **8** and **9**. P_0 equals atmospheric pressure, and P_1 equals the full supply pressure at **39**. AC represents the distal end of the gaiter, i.e., the location of line A in FIG. **6** and line C in FIG. **8**; BD represents the proximal end of the gaiter, i.e., the location of line B in FIG. **6** and line D in FIG. **8**. Function **52** represents the pressure distribution over the length AC or BD when vacuum is applied at **50**. Functions **53** represent four alternative pressure distributions when atmospheric pressure is applied at **50**; which of them actually applies in a particular case will depend upon many factors including the construction of the stock, the shape of the limb within it, and the relative values of P_0 and P_1. The important thing is that all these functions maintain a positive or zero gradient between AC and BD. If the gradient becomes negative anywhere within this region there is danger of creating a tourniquet effect, since fluid in some distal part of the limb cannot travel to the main body of the patient without passing through a region subjected to a higher pressure.

We claim:

1. Limb treatment apparatus comprising a container, means for supplying gas under pressure to the interior of said container, said container having a resilient wall section defining an aperture adapted to receive a limb to be treated, said wall section having a circumference normally less than that of said limb and being stretchable so as to yield to extend the aperture when a limb intrudes and, when thus stretched, forming a leaking seal between itself and said limb, the part of the stretchable wall section defining the aperture being in the form of a gaiter that surrounds an intruding limb snugly over a length of said limb, whereby the leaking seal may expose the surrounded length of limb to a pressure gradient when gas is supplied under pressure to the interior of the container.

2. Limb treatment apparatus according to claim **1**, in which the gaiter is positioned so that its free end registers with the proximal end of the limb.

3. Limb treatment apparatus comprising a container, means for supplying gas under pressure to the interior of said container, said container having a wall section defining an aperture adapted to receive a limb to be treated, said wall section being deflectable so as to yield to extend the aperture when a limb intrudes and, when thus deflected, forming a leaking seal between itself and said limb, the part of the deflectable wall section defining the aperture being in the form of a gaiter that surrounds an intruding limb snugly over a length of said limb, whereby the leaking seal may expose the surrounded length of limb to a pressure gradient when gas is supplied under pressure to the interior of the container, a jacket enclosing the gaiter section of the wall, and a source of fluid under variable pressure is connected to the jacket, whereby to vary the clearance of the leaking seal and so modify the pressure gradient to which the gripped length of limb is exposed.

4. Limb treatment apparatus according to claim **3**, in which the source of fluid is adapted to apply a vacuum to the jacket to lift the gaiter clear of the limb whereby to reduce the gradient to zero.

5. Limb treatment apparatus according to claim **1**, having control means to regulate the supply of gas to the interior of the container, said means being operable to supply alternate pulses of atmospheric pressure and a higher than atmospheric pressure and thereby subject the limb to a vascular pumping action.

6. Limb treatment apparatus comprising a container, means for supplying gas under pressure to the interior of said container, said container having a wall section defining an aperture adapted to receive a limb to be treated, said wall section being deflectable so as to yield to extend the aperture when a limb intrudes and, when thus deflected, forming a leaking seal between itself and said limb, said seal being adapted to exert no greater pressure upon the part of the limb that lies within it than is exerted upon the rest of the limb lying within the container, a substantial part of the wall of the container being lightweight and flexible, and a harness connected to the container by which it can be attached to the owner of the limb being treated, whereby to allow that owner some mobility while treatment proceeds.

* * * * *