

- [54] **POSITIONING AID**
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Related U.S. Application Data

- [63] Continuation-in-part of Ser. No. 853,661, Aug. 28, 1969, abandoned.

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137/525.3

- [51] Int. Cl. **A61f 5/02**

- [58] Field of Search..... 128/78, 87, DIG. 20,
128/89; 137/525.3, 614.2; 251/362

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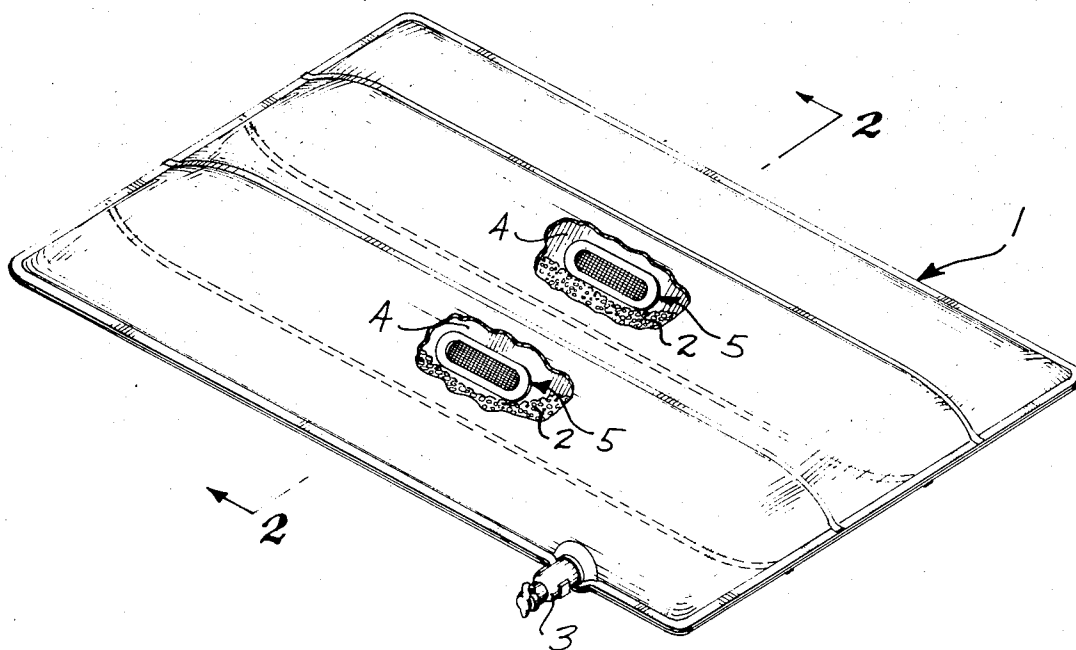
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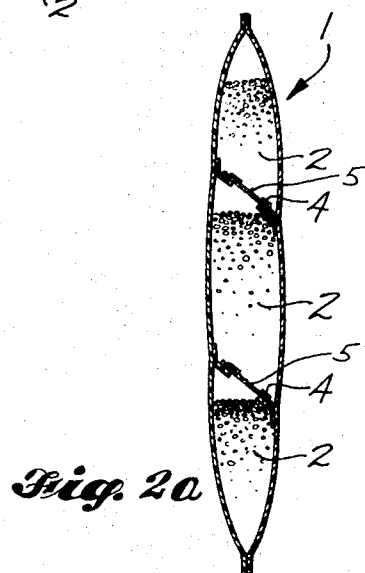
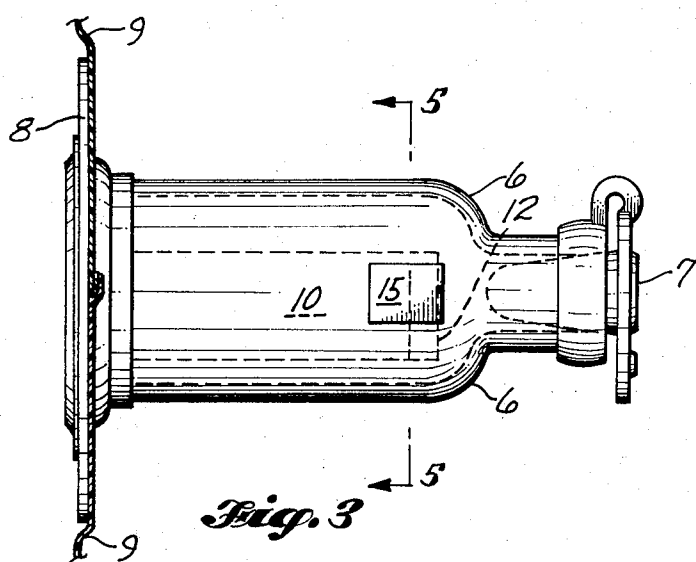
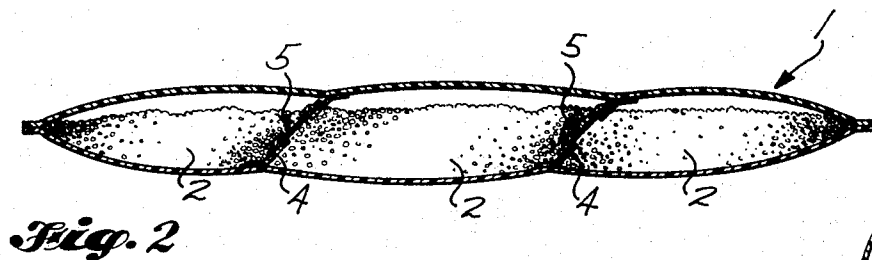
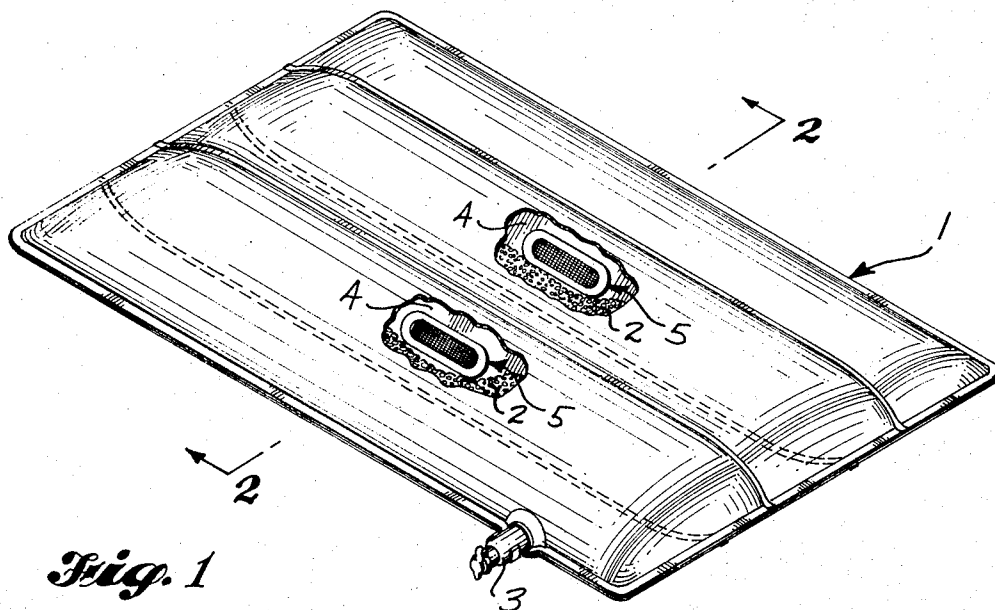
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[57] **ABSTRACT**

A positioning aid for restraining or immobilizing a part of the body of a medical patient comprising an air-tight bag of flexible, impervious material; a charge of elastically deformable spherulic beads of expanded polystyrene confined within the bag; and a self-closing valve communicating with the interior of said bag for evacuating air therefrom. Material proportions of the beads are of respectively different diameters. The bag is divided into a plurality of compartments by partitions extending obliquely between opposing walls of the bag. The partitions, which maintain the particles evenly distributed in the bag, are adapted to permit air-flow between the compartments and to prevent passage of the beads therebetween. When the positioning aid is evacuated after having been conformed to a portion of a patient's body, the aid becomes rigid while maintaining its pre-evacuation shape.

16 Claims, 16 Drawing Figures





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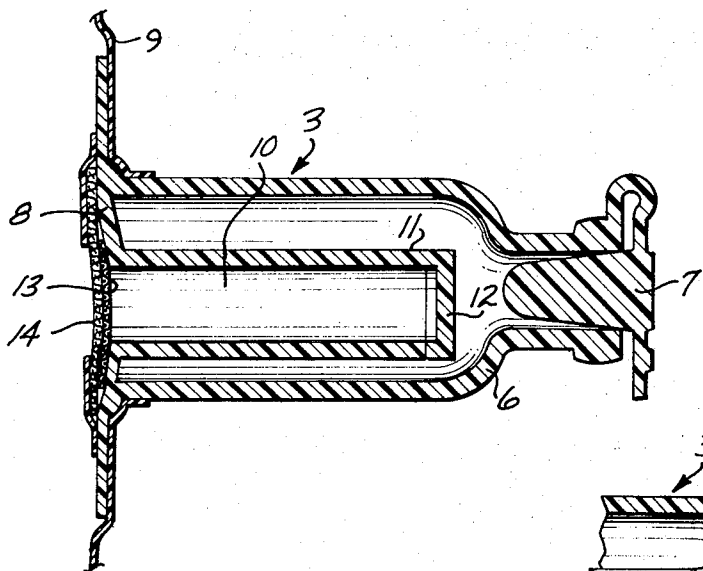


Fig. 4

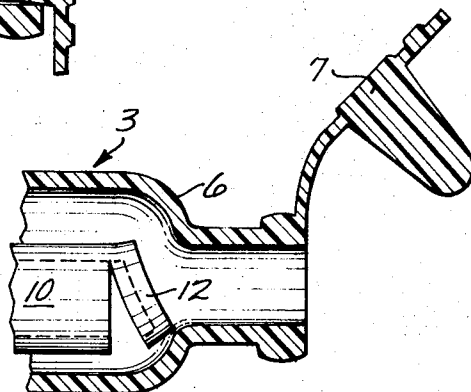


Fig. 6

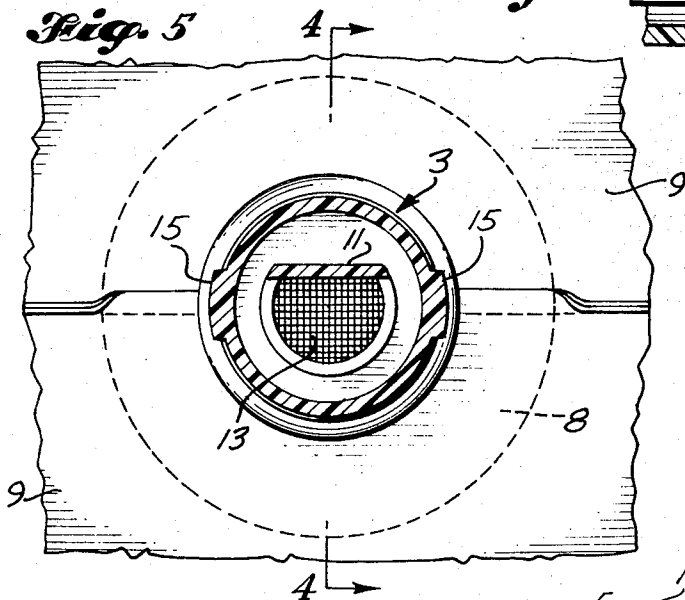


Fig. 5

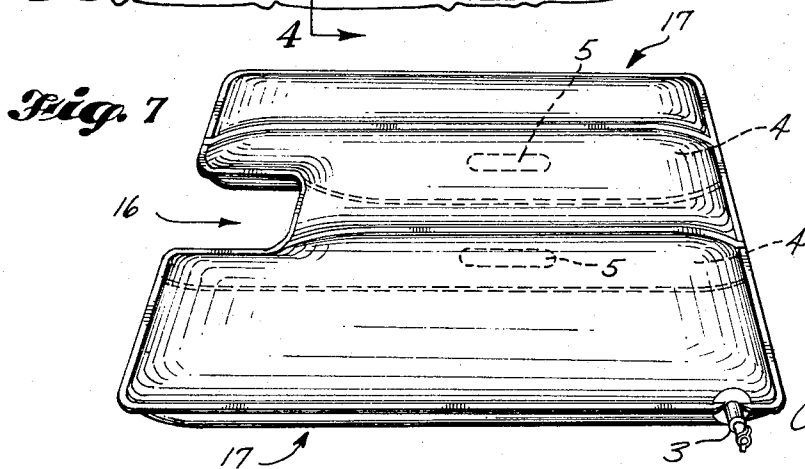


Fig. 7

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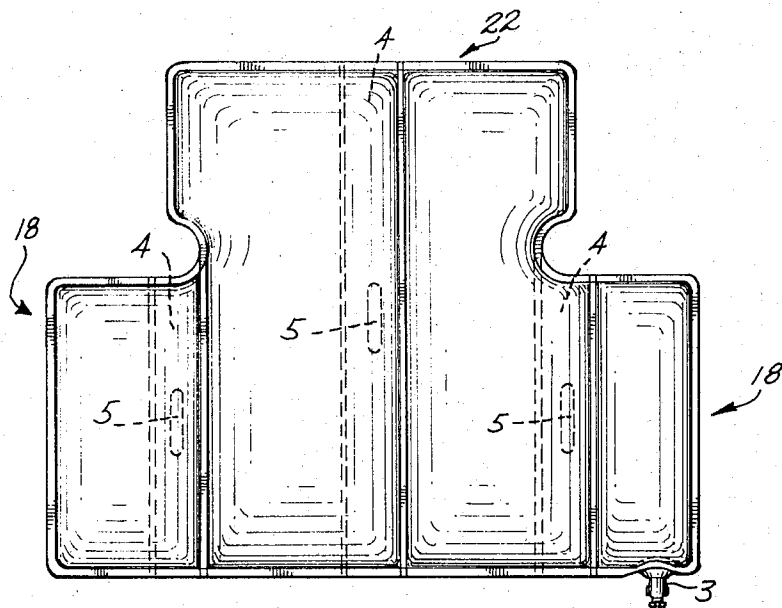


Fig. 8

Fig. 9

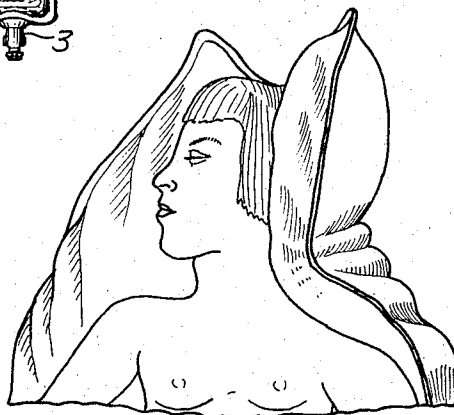


Fig. 10a

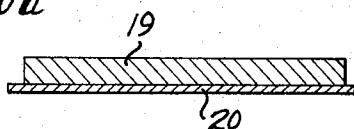


Fig. 10b

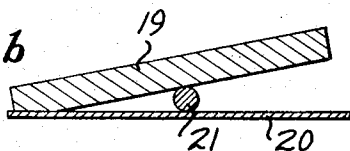


Fig. 10c

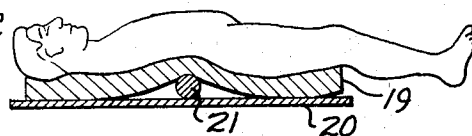
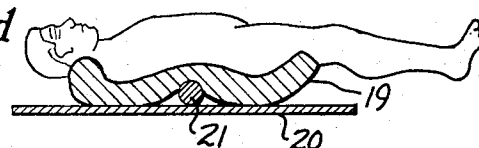
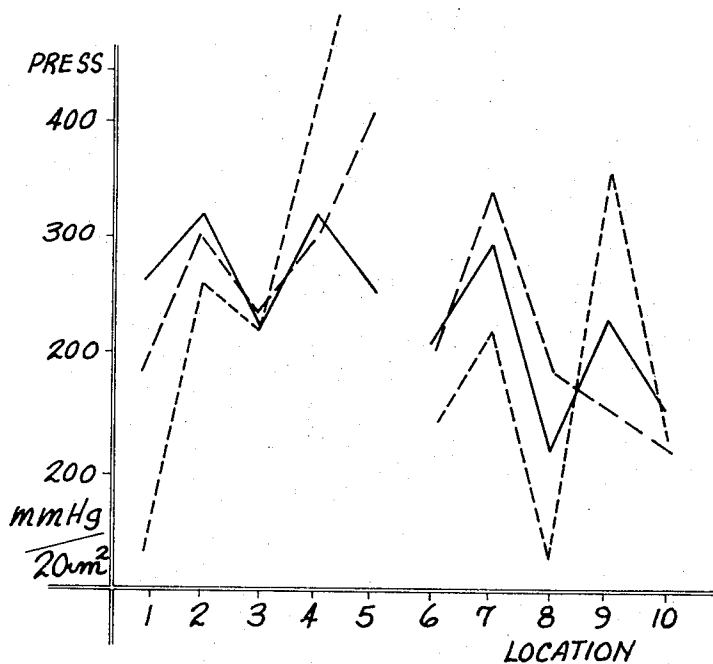
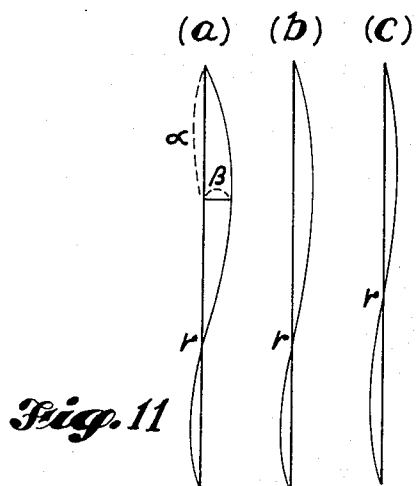


Fig. 10d



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POSITIONING AID

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of my co-pending application Ser. No. 853,661, filed Aug. 28, 1969, for "Positioning Aid" now abandoned.

BACKGROUND AND SUMMARY OF THE INVENTION

This invention relates to an improved positioning aid for supporting, restraining and/or immobilizing a portion of the body of a medical patient as long as may be needed for conducting radiography, therapy, surgery, patient transport and the like.

Vacuum-actuated positioning aids consisting of a flexible impervious bag containing small particles which consolidate into a rigid mass when the bag is evacuated are known in the art. See, for example, U. S. Pat. No. 3,212,497 to Dickinson.

It is an object of this invention to provide a vacuum-actuated positioning aid of an improved construction. An important object of this invention is to devise a positioning aid of the general type described which is readily formable into any of varying configurations and yet is so constituted as to provide a higher degree of form stability upon evacuation than is obtainable with prior positioning aids. Additionally, it is an object to provide an improved positioning aid capable of assuming and rigidly maintaining minute variations of contour by corresponding arrangements and rearrangements of small spherulic beads. To such ends, the invention includes charging the bag with spherulic beads within a predetermined general range of sizes and, within that range, assuring that substantial proportions of the total are respectively each of materially different sizes. For practical optimum results several sizes are contemplated and the proportions of beads in the lower and mid-range sizes should be substantially greater than that of beads at the high end of the range. Mobility of the bead to conform to minutely varying shapes and stable interfit (both bead-to-bead and bead-to-bag) with uniform stress distribution among the beads are materially improved over positioning aids containing beads of substantially equal size.

Another object hereof is to improve the compartmentation of a positioning aid bag with respect to cooperative distribution of the masses of beads in the respective compartments. More particularly, it is an object to provide a simple bag construction wherein the compartments may be only partially filled with beads so that before evacuation the bag is highly flexible and readily conformable to various shapes and after evacuation does not present difficulty with lack of solidity due to void spaces in the partially filled compartments. To this end, partitions extending obliquely between and interjoining opposing walls of the bag held assure mutual reinforcing overlap of the bead masses in adjacent compartments.

Still another object hereof is to provide a safe, reliable, inexpensive and readily operable vacuum valve for positioning aids of the types described. Moreover, it is an object to achieve such a valve which will not scratch or injure a patient and which may be made without exterior metal parts that can create sparks in a surgical operating room. A related object is to provide such a valve which can be opened manually by pinching it in a certain manner, which will automati-

cally become and remain firmly sealed against loss of vacuum in the bag until so operated, and which is so constructed as to preclude accidental operation by reason of normal pressures and stresses applied to it in the handling or use of the positioning aid.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an isometric view, with parts broken away, of one embodiment of the positioning aid according to this invention.

FIG. 2 is an enlarged section view along line 2—2 of FIG. 1.

FIG. 2a is a section view of the positioning aid of FIG. 1 oriented vertically.

FIG. 3 is an enlarged side view of the valve on the positioning aid of FIG. 1.

FIG. 4 is a section view along line 4—4 of FIG. 5 showing the valve in its closed mode.

FIG. 5 is a section view along line 5—5 of FIG. 3.

FIG. 6 is a partial section view of the valve of FIG. 3 in its open mode.

FIGS. 7 and 8 are isometric views of two other embodiments of the positioning aid according to this invention.

FIG. 9 is a perspective view of the positioning aid of FIG. 1 as applied to the postoperative orthotic restraint of a child after desmotomy of myogenic torticollis.

FIGS. 10a to 10d illustrate the preparation of a recurrence bed in dorsal decubitus using a positioning aid of this invention.

FIG. 11 shows dorsal spine curves for (a) normal standing position, (b) dorsal decubitus with a positioning aid of this invention and (c) dorsal decubitus with a plaster of Paris bed.

FIG. 12 is a graph showing results of comparative tests on the pressure of the dorsal surface of a patient lying on a mattress, a plaster of Paris bed and a positioning aid of this invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIGS. 1 - 3, there is shown one embodiment of the positioning aid of this invention. It comprises a generally rectangular, air-tight bag 1 of flexible, impervious material, containing a charge of elastically deformable spherulic beads 2. The bag is equipped with a self-closing valve 3. The interior of the bag is divided into three compartments by two partitions 4 extending lengthwise of the bag and obliquely between the bag walls. Each compartment contains a fraction of the total charge of beads. So that the aid is readily conformable to various portions of a patient's body, each compartment is only partially filled with beads. Screened openings 5 are provided in the partitions so that air can flow between compartments while the beads cannot. The partitions maintain the beads more or less evenly distributed throughout the bag. As shown in FIG. 2a, orientation of the partitions obliquely to the bag walls reduces the effective thickness of each compartment along the partitions and thereby assures a more even distribution of beads in each compartment when the bag is so positioned that the beads tend to accumulate along the partitions.

FIGS. 3 - 6 show the details of a self-closing valve which is especially preferred for use in the positioning aid of this invention. Except as indicated, all of the valve parts are made of the same soft, flexible material, such as polyvinyl chloride. The valve consists of a cylin-

drical body 6 having an integral plug 7 secured to one end and the circular valve base 8 to the other, the valve base being sealed to the inner side of the bag wall 9. An inner cylinder 10 having one flat side 11 (FIG. 5) extends within and is enclosed by the valve body. The inner cylinder is provided at one end with an integral circular lid 12. The lid is hinged to the flattened part of the periphery of the inner cylinder so as to be moveable thereabout. The other end of the inner cylinder is joined with the valve base 8 and is in communication with the interior of the bag through an opening in the base. A layer of fine mesh wire screen 13 and a layer of loosely woven cloth 14 are positioned over this hole and are secured to the base. The screen and cloth prevent the beads from being drawn from the bag when a vacuum is applied to the valve.

In FIGS. 3 and 4 the valve is in its closed position with the plug 7 being inserted in the end of the valve body and the hinged lid 12 abutting against and closing the free end of the inner cylinder. When the positioning aid is to be evacuated, plug 7 is removed from the opening in the valve body (FIG. 6) and the valve is then connected to a vacuum source. Application of the vacuum causes the pressure on the outer side of the lid to become less than on the inner side and the lid moves to its open position as shown in FIG. 6. When the externally applied vacuum is interrupted, the lid 12 automatically returns to its closed position because of its own resilience and the greater pressure on its outer side. The plug 7 is then inserted into the valve body providing a second seal.

When it is desired to release the vacuum within the positioning aid, the plug 7 is removed and the square, raised areas 15 on the outside of the valve body are squeezed with the thumb and index finger. Sufficient pressure is applied to deform both the valve body and the inner cylinder, deformation of the latter causing the lid 12 to open (as shown in FIG. 6), causing the vacuum to be released. The plug 7, when inserted in the valve body, prevents the vacuum from being released even if the valve body and inner cylinder should be accidentally compressed sufficiently to open the lid.

The valve of this invention is especially dependable and convenient to operate, provides a substantial margin of safety against accidental release of the vacuum within the bag and, because of its soft, flexible construction, cannot injure the patient. Furthermore, the valve can be inexpensively manufactured as an integral unit, except for the screen and cloth, by well-known injection molding techniques.

The material from which the bag portion of the aid of this invention is manufactured should have good flexibility, durability and air-tightness. Suitable sheet materials include soft polyvinyl chloride, nylon, polypropylene, polyethylene, tetrafluoroethylene resins, urethane, copolymers of ethylene and vinyl acetate, soft A.B.S. resin acrylic esters, silicon rubber, and mixtures of polyvinyl chloride and synthetic rubber. Plasticizers, flame retardants, pigments and lubricants can also be included. A preferred sheet material comprises a mixture of from 70 to 80 parts by weight of polyvinyl chloride and from 20 to 30 parts by weight of synthetic rubber. A 75:25 ratio is especially preferred. Sheets of this composition exhibit excellent flexibility and a high coefficient of friction. Flexibility is of importance because the bag must conform well to the shape of a patient's body. The high coefficient of friction of the bag

material increases the friction between the beads and the bag wall which in turn increases the stability of the rigid structure formed when the positioning aid is evacuated.

The beads used in the positioning aid of this invention must be sufficiently rigid to withstand the stresses which result when they interengage upon evacuation of the bag. The beads must also have a high mechanical strength so that the aid can be repeatedly used without accompanying attrition or fracture of the beads, and should also be elastically deformable such that when the bag is evacuated they can move freely into close engagement to thereby form a stable, rigid structure.

Beads of expanded plastic materials, such as polystyrene and polyvinyl chloride, are preferred because of their high mechanical strength, elastic deformability and low specific gravity. Beads of expanded polystyrene are especially preferred. The expression "specific gravity" is intended herein to mean a true specific gravity. Thus, when such beads are made hollow, the specific gravity of the bead is represented by its weight divided by its total volume including the hollow spaces therein. According to the invention, the specific gravity of bead should be in the range of from about 0.1 and about 0.6. Such values are readily attainable with foamed synthetic resins, although other materials can be used for granules when they have a low specific gravity in the range specified above and satisfy the mechanical strength and elastic deformability requirements. A specific gravity of foamed synthetic resin materially less than 0.1 is only achievable when the resin is excessively foamed, and the resulting beads are soft and not effective for the purpose of the invention. When the specific gravity materially exceeds 0.6, the formability of the aid, its form stability when evacuated and its transparency to X-rays are diminished, and the aid cannot be conveniently handled because of its increased weight.

In order to insure that the positioning aid fits well to the patient and remains stable when evacuated, the beads should be from about 1 to about 5 millimeters in diameter. Beads which are uniform in size and shape can be used, but it has been found that an aid containing a mixture of substantial portions of beads of at least two materially different sizes within the indicated range provides more uniform and stable support to the patient than does an identical aid containing beads which are all of one size. Preferably, the beads are of differing sizes distributed across the range of from 1 to 5 millimeters, with sizes in the lower and middle portions of this range predominating. The following is an especially preferred distribution of bead sizes:

Diameter (mm.)	% by Volume
1	20
2	30
3	30
4	10
5	10

The vacuum pump used to evacuate the positioning aid may be either manually operated or power driven, and preferably has a displacement capability better than 20 liters per minute so that the aid can be evacuated within a short period of less than thirty seconds. Desirably the pump is one capable of attaining a degree of vacuum on the order of 10 to 50 mm Hg.

In one instance, an aid of this invention was initially evacuated to a pressure of between 10 and 50 mm Hg

and remained below half an atmosphere pressure after 3 days of use. It was found that repeated use had a tendency to maintain the vacuum over an increasing time period. Also, expanded plastic beads which has been kept in storage for an extended period, for example 1 month, were charged into the positioning aid, the aid maintained a usable degree of vacuum over an increased period as compared with a corresponding aid in which freshly prepared beads were charged. Therefore, it should be understood that the particular pressure to which the interior space of the positioning aid is evacuated depends upon various factors, including the material for the bead and bag body as well as the particular applications intended. It has been found that the positioning aid of the invention is operable with its internal pressure below half an atmosphere pressure, even though it should be obvious that the lower the pressure, the better the aid maintains its form.

FIGS. 7 and 8 show two other useful shapes in which the positioning aid of this invention can be constructed. The valves 3 and partition walls 4 in these two embodiments are the same as in the embodiment discussed above. The aid shown in FIG. 7 is particularly useful for supporting the torso of a patient in a normal lateral position, one shoulder of the patient being situated in the recess 16 on one end of the aid and sides of the aid 17 being folded upwardly along the patient's front and back. The aid shown in FIG. 9 is useful for supporting the torso of a patient in a ¾ lateral or kidney position with the sides of the aid 18 folded upwardly along the patient's front and back and the narrow area of the aid 22 supporting the patient's head and shoulder.

FIG. 9 illustrates a positioning aid of this invention applied to the restraint of a child after desmotomy of myogenic torticollis. It will be noted that the aid shown facilitates postoperative traumatotherapy and daily strengthening through orthotherapy.

FIGS. 10a - 10d illustrate the preparation of a recurvature bed in dorsal decubitus using a positioning aid according to this invention. The positioning aid 19 is placed on a board 20 and is first evacuated so as to be essentially rigid (FIG. 10a). Then a hard pillow 21 is inserted between the rigid aid and board at a location where it is desired to provide recurvature (FIG. 10b). A patient is caused to lie down on the aid in dorsal decubitus (FIG. 10c) and air is allowed to enter the interior of the aid through the valve (not shown). The aid thereby becomes limp so that the body of the patient sinks into the aid, whereupon parts of the aid are fitted around the shoulders and waist of the patient (FIG. 10d). After any required correction of the patient's position, the valve of the aid is connected to a vacuum pump to evacuate the aid. It is also possible to evacuate and solidify the aid during the interval of correcting the patient's position. The purpose of initially evacuating the aid is to prevent beads from being displaced away from the space directly below the patient's body when the aid is limp. However, if partition walls are provided in the interior of the bag body as described previously, the initial evacuation is unnecessary.

In order to examine the state of a spine and blood circulation during the dorsal fixation on the positioning aid, a patient's spinal curve (FIG. 11) and back pressure (FIG. 12) were measured for five cases indicated below.

Case	Disease	Age	Sex	(kg)
1	Normal	27	Male	65
2	Nerve paralysis of arm	21	"	55
3	Hernia of intervertebral disc	15	"	53
4	Spondylolysis	21	"	54
5	Spondylolysis	28	"	51

In FIG. 11, curve (a) refers to normal standing position, curve (b) to dorsal position on the positioning aid of the invention, and curve (c) to dorsal position on plaster of Paris bed. It will be noted that the curve (b) has a lower backward curvature of thoracic vertebra (β/α) than curve (a), but the point (γ), the transition from backward curvature of the thoracic vertebra to forward curvature of lumbar vertebra, remains unchanged. In the curve (c), the backward curvature becomes even less and the point of transition shifts upwardly. All of five cases showed similar results. It is known that backward curvature of spinal curves measured in dorsal and ventral decubitus is less than that in standing position and that the point of transition measured in standing position remains unchanged in dorsal decubitus, but shifts toward the head in ventral decubitus. This fact indicates that the curve (b) represents physiological dorsal decubitus, while the curve (c) physiological ventral decubitus. Thus, it will be appreciated that dorsal fixation by means of the positioning aid of the invention maintains the physiological curvature fairly well so that a patient does not suffer from pain due to forced fixation.

FIG. 12 shows pressure per 20 cm² on a patient's dorsal surface with an ordinary mattress (broken lines), plaster of Paris bed (claim lines) and the positioning aid of the invention (solid lines). An electro-manometer was used to measure pressure at 15 points, namely, five points on the dorsomedian line and five points on the right and left scapular lines, as indicated below.

Number of Points	Position Measured
1.	Spinous process on vertebra prominens, median line
2.	Spinous process on 5th thoracic vertebra, median line
3.	Spinous process on 12th thoracic vertebra, median line
4.	Spinous process on basilar vertebra, median line
5.	Lower sacrum, median line
6.	Infraspinous scapula, scapular line
7.	Anguluinferior scapula, scapular line
8.	Floating rib, scapular line
9.	Ilium, scapular line
10.	Upper buttock, scapular line

FIG. 12 shows that the pressure varies considerably along the vertebra when the patient lies on a mattress (broken lines), and that extremely high pressures were observed at positions where bedsores are often found. The amplitude of oscillation or variation of pressure is greatly decreased with the positioning aid when compared with a mattress, and is still less than that in a plaster of Paris bed. Though the difference of pressure between the positioning aid and the plaster of Paris bed is small as illustrated in FIG. 12, it was observed that the patient feels more comfortable in the positioning aid than in the plaster of Paris bed because of the softer texture of the positioning aid.

It will be noted that the positioning aid according to the invention can be applied to many fields of medical treatments and diagnosis. A patient supported and restrained by the positioning aid can be X-rayed while the portion of his body to be examined is covered by the

aid. Little or no shadowing influence is observed in the X-ray photograph.

What is claimed is:

1. A vacuum-actuated positioning aid comprising a flexible, impervious bag; a charge of elastically deformable spherulic beads confined within said bag, said beads having diameters of from about 1 to about 5 millimeters and specific gravities of from about 0.1 to about 0.6, said charge being comprised of a mixture of at least two portions of beads, each portion comprising at least ten percent of the volume of said charge and the beads in one portion being at least one millimeter smaller in diameters than the beads in the other portion; and a valve communicating with the interior of said bag for evacuating air therefrom whereupon said beads interengage to form a rigid structure.

2. The positioning aid of claim 1 wherein said beads are comprised of an expanded plastic material.

3. The positioning aid of claim 1 wherein said beads are comprised of an expanded plastic material containing an elastomer.

4. A positioning aid of claim 1 wherein said beads are comprised of expanded polystyrene.

5. The positioning aid of claim 1 wherein said charge is comprised of a mixture of beads with predetermined fractional proportions of the charge being of beads having different diameters distributed substantially across the range of from 1 to 5 millimeters.

6. The positioning aid of claim 5 wherein by volume the proportions of beads of low- and mid-range diameters predominate.

7. The positioning aid of claim 1 wherein by volume the proportions of beads of low- and mid-range diameters predominate.

8. The positioning aid of claim 1 wherein said flexible, impervious material is comprised of a mixture of polyvinyl chloride and synthetic rubber.

9. The positioning aid of claim 1 wherein said bag includes a pair of opposing walls and a partition secured to and extending obliquely between said walls, said partition dividing the interior of said bag into two, overlapping compartments, portions of said charge of beads being confined within each of said compartments, and said partition being adapted to permit the flow of air and prevent the flow of beads from one bag compartment to another.

10. The positioning aid of claim 9 wherein said beads are comprised of an expanded plastic material.

11. The positioning aid of claim 9 wherein said charge is comprised of a mixture of beads with predetermined fractional proportions of the charge being of beads having different diameters distributed substantially across the range of from 1 to 5 millimeters.

12. A vacuum-actuated positioning aid comprising a flexible, impervious bag; a charge of elastically deformable spherulic beads confined within said bag, said beads having diameters of from about 1 to about 5 millimeters and specific gravities of from about 0.1 to about 0.6, said charge being comprised of a mixture of at least two substantial portions of beads having materially different diameters; and a valve communicating with the interior of said bag for evacuating air therefrom whereupon said beads interengage to form a rigid structure, said valve comprising a soft, flexible cylindrical valve body having first and second ends, means for opening and closing said first end, a soft flexible inner cylinder extending within said valve body and having

first and second ends respectively proximate said first and second ends of said valve body, said second end of said inner cylinder communicating with the interior of said bag, a lid secured to a segment of the periphery of said first end of said inner cylinder, said lid being resiliently movable about said segment between a closed position abutting against and closing said first end of said inner cylinder and an open nonabutting position, movement of said lid being responsive to pressure differentials on opposite sides thereof, and means for forming an air-tight seal between the inside of said valve body and the outside of said inner cylinder proximate the respective second ends thereof.

13. A vacuum-actuated positioning aid comprising a flexible, impervious bag, said bag having first and second opposing walls; a charge of elastically deformable spherulic beads confined within and partially filling said bag; a partition secured to and extending obliquely between said walls, said partition dividing the interior of said bag into two, overlapping compartments, portions of said charge of beads being disposed within each of said compartments, and said partition being adapted to permit the flow of air and prevent the flow of said beads from one bag compartment to another; and a valve communicating with the interior of said bag for evacuating air therefrom whereupon said beads interengage to form a rigid structure.

14. A vacuum-actuated positioning aid comprising an air-tight bag of flexible, impervious sheet material; a charge of elastically deformable spherulic beads disposed within said bag; and a valve communicating with the interior of said bag for evacuating air therefrom, said valve comprising a soft, flexible cylindrical valve body having first and second ends; means for opening and closing said first end; a soft flexible inner cylinder extending within said valve body and having first and second ends respectively proximate said first and second ends of said valve body; said second end of said inner cylinder communicating with the interior of said bag; a lid secured to a segment of the periphery of said first end of said inner cylinder, said lid being resiliently movable about said segment between a closed position abutting against and closing said first end of said inner cylinder and an open non-abutting position, movement of said lid being responsive to pressure differentials on opposite sides thereof; and means for forming an air-tight seal between the inside of said valve body and the outside of said inner cylinder proximate the respective second ends thereof.

15. The positioning aid of claim 14 wherein said valve is of a substantially one-piece molded construction.

16. A positioning aid comprising a substantially flat, flexible, impervious bag comprised of first and second opposing walls secured together about their respective peripheries, and a flexible partition extending across the interior of said bag, said partition being secured along its length to each of said walls and being oriented obliquely to each of said walls so as to divide the interior of said bag into first and second compartments, which compartments are mutually overlapping along said partition; a charge of elastically deformable spherulic beads confined within said bag, portions of said charge of beads being disposed within and partially filling each of said compartments, said partition being adapted to permit the flow of air and prevent the flow of beads from one compartment to another; and a valve communicating with the interior of said bag for evacuating air therefrom, whereupon said beads interengage to form a rigid structure.

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