

[54] CARDIOVASCULAR ASSIST DEVICE

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[58] Field of Search 128/24, 64, 87, DIG. 20

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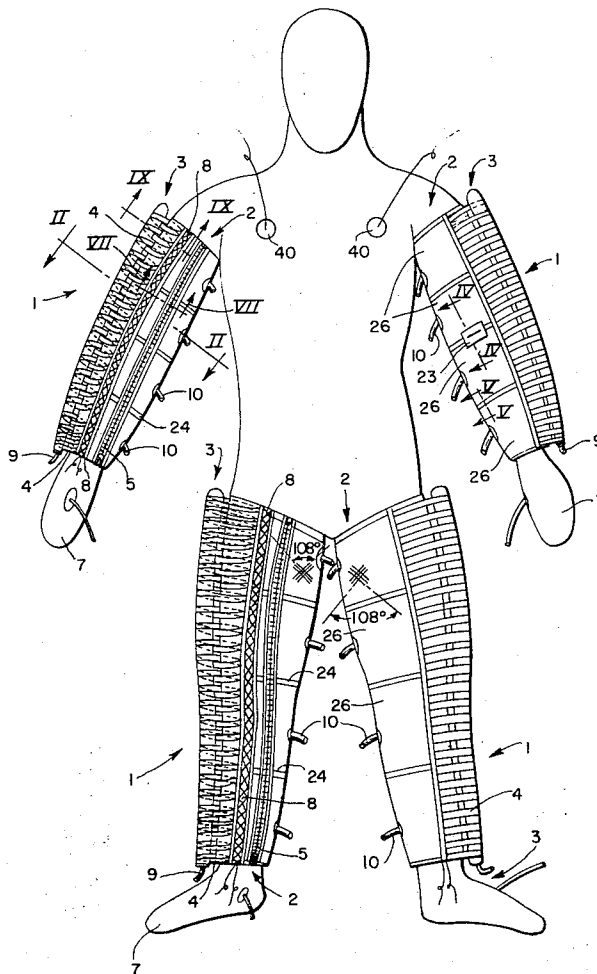
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[57] ABSTRACT

A cardiovascular assist device for producing an inwardly orienting pulsating pressure circumferentially to the entire length of each extremity of a patient, including a main body portion surrounding the extremity and a lateral body portion being inflatable to tightly constrict the main body portion about the extremity before pulsation. The lateral body portion includes a single inflatable tube having connecting tapes extending substantially entirely circumferentially therearound and oppositely circumferentially at least partially around said main body portion to terminal ends secured to the main body portion. The main body portion includes an outer restraint material reinforced by a plurality of circumferentially extending and a plurality of longitudinally extending restraint tapes, two sheets of resilient material circumferentially bonded together at longitudinal intervals and longitudinally along seams to produce a plurality of overlapping circumferentially extending inflatable bladders, which are longitudinally spaced from each other, an inner pouch material and a plurality of fluid couplings communicating with each bladder and inflatable tube. Mittens are provided to close one end of each main body portion and similarly constructed to provide an inwardly pulsating pressure to the respective hand or foot of the patient. The main body portions and mittens may be donned and doffed by means of respective longitudinally extending fasteners, and thereafter manually circumferentially constricted by means of longitudinally extending lacings prior to the pressure constriction caused by inflating the lateral body portion.

23 Claims, 12 Drawing Figures



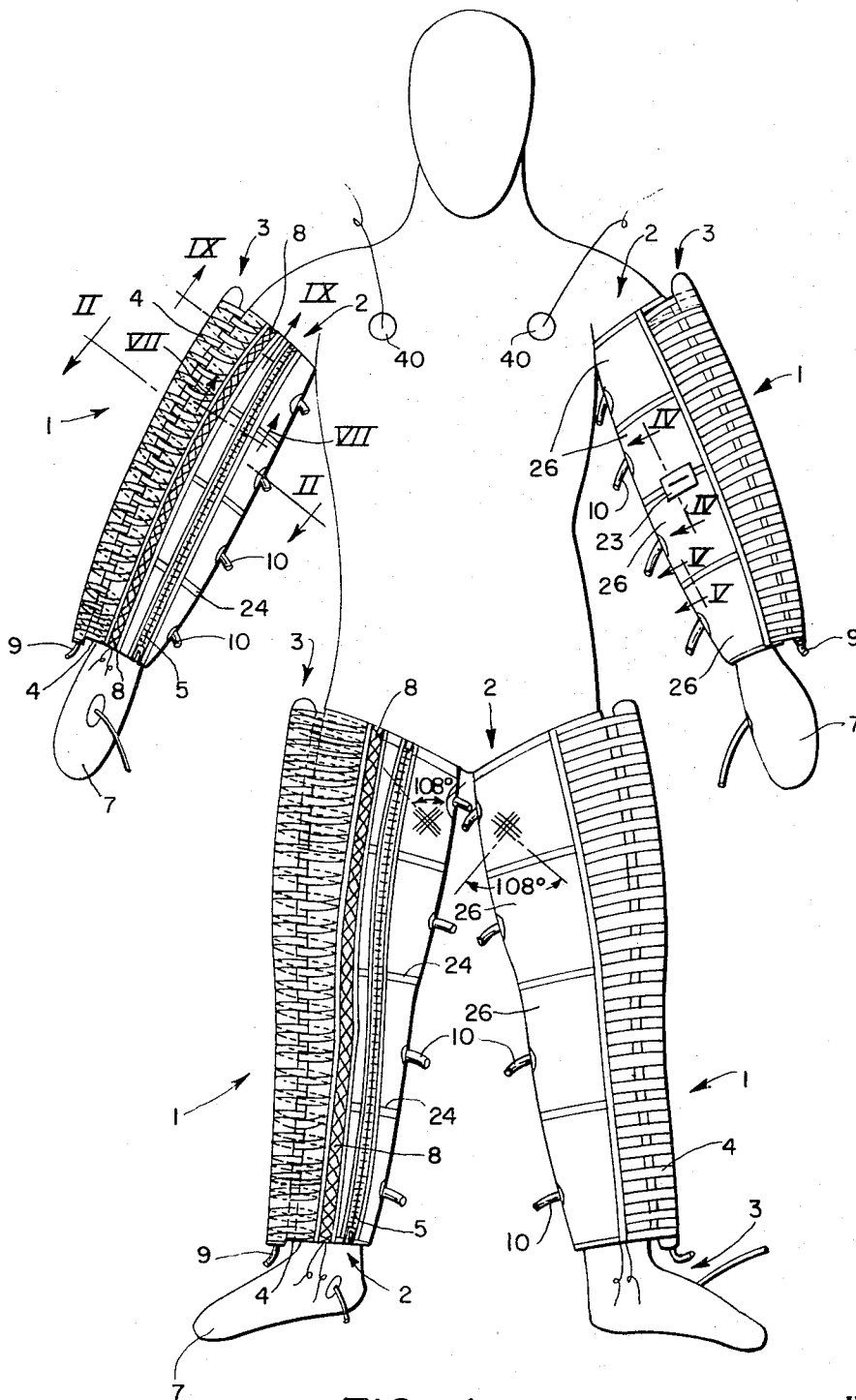
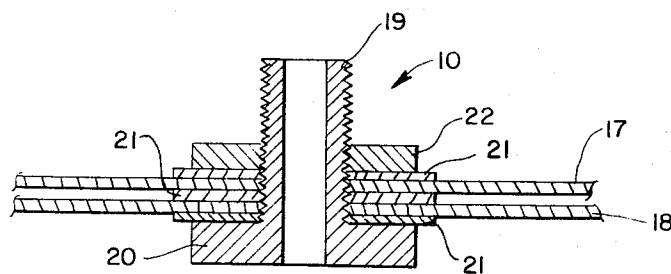
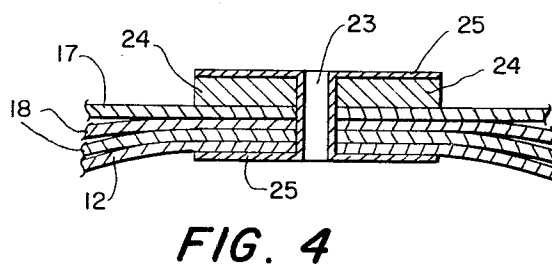
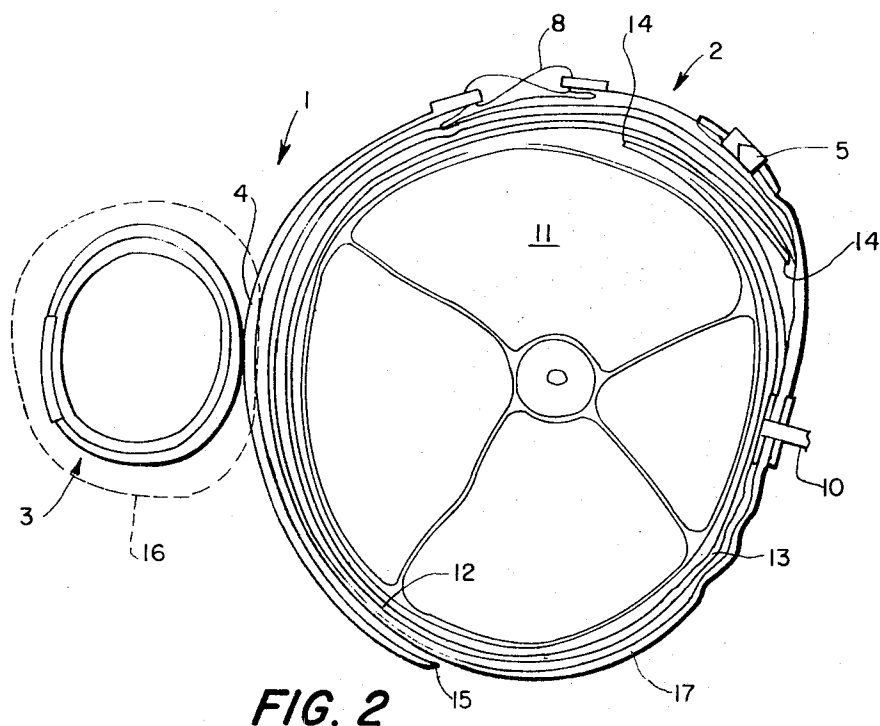


FIG. 1

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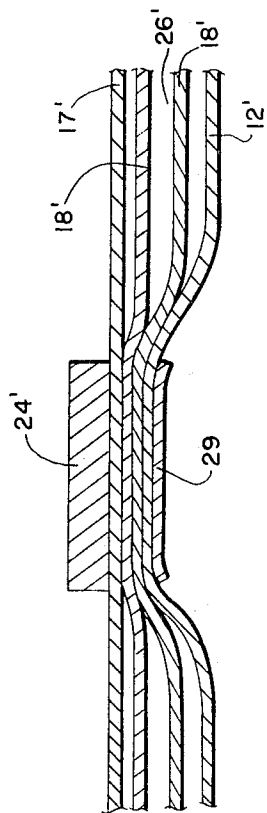


FIG. 5

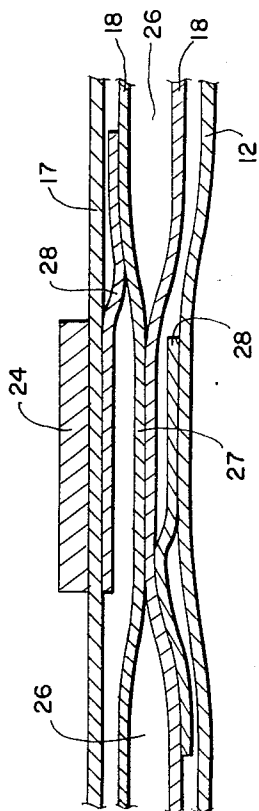


FIG. 6

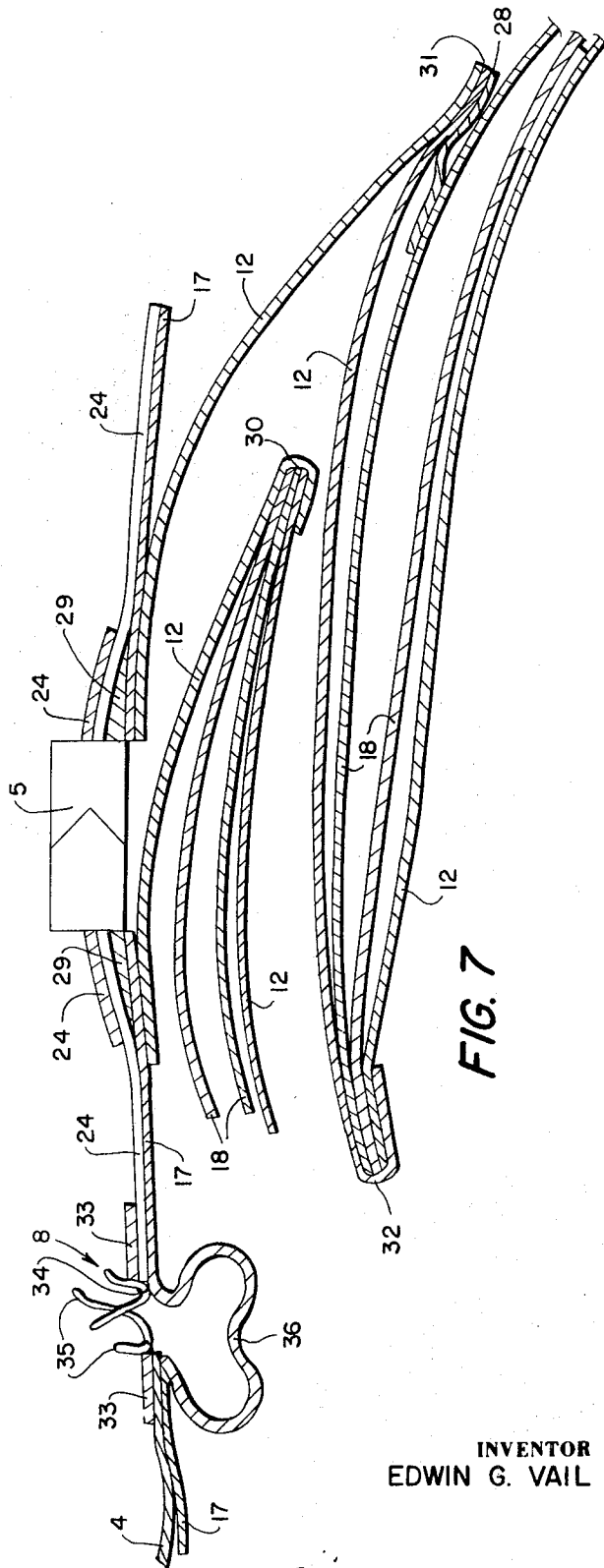


FIG. 7

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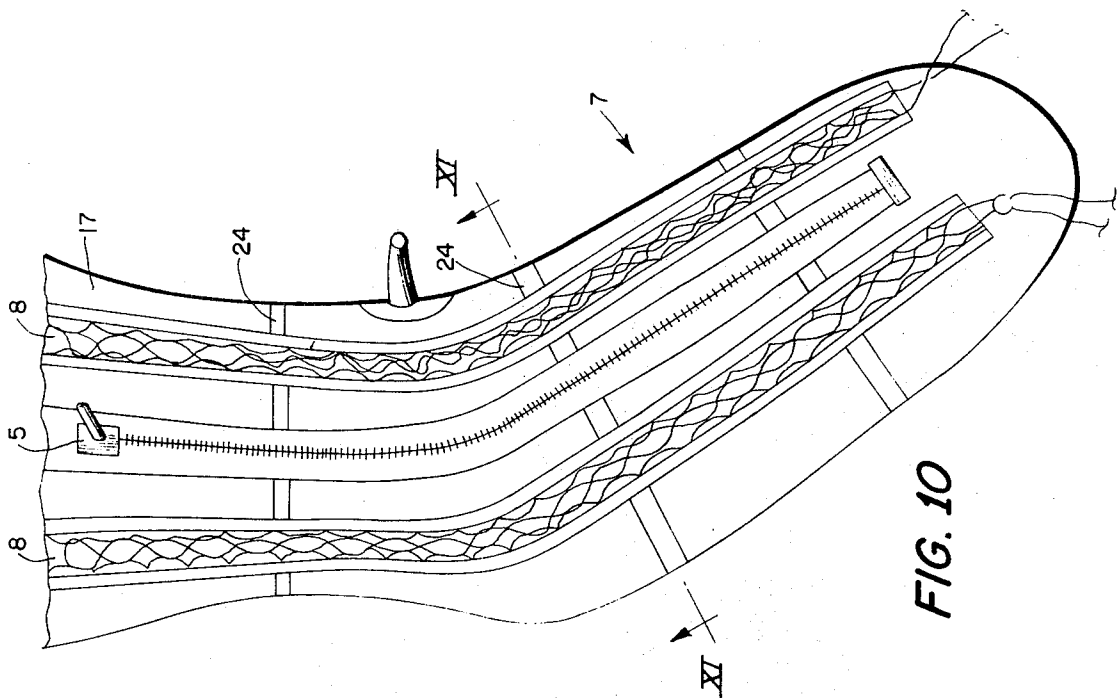


FIG. 10

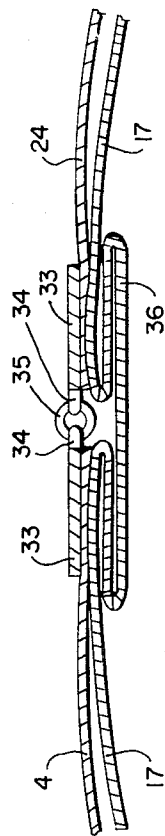


FIG. 8

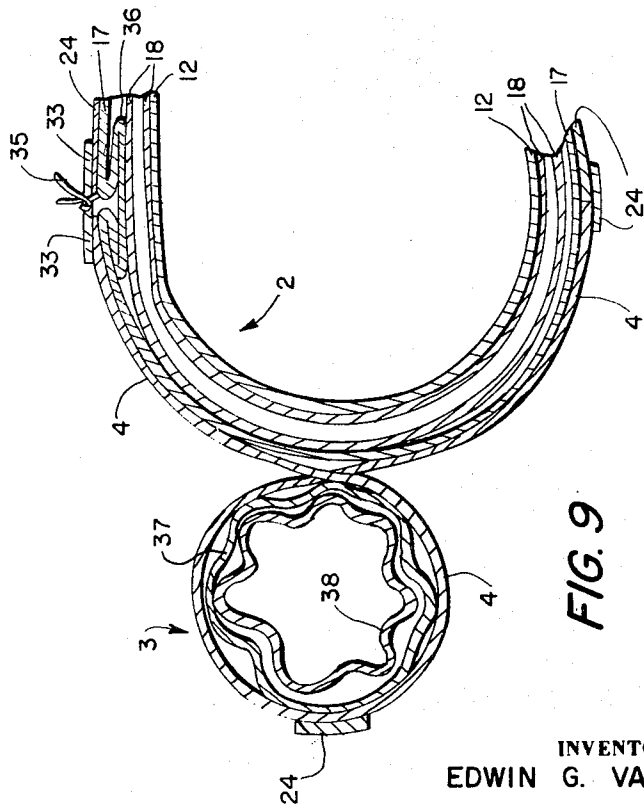


FIG. 9

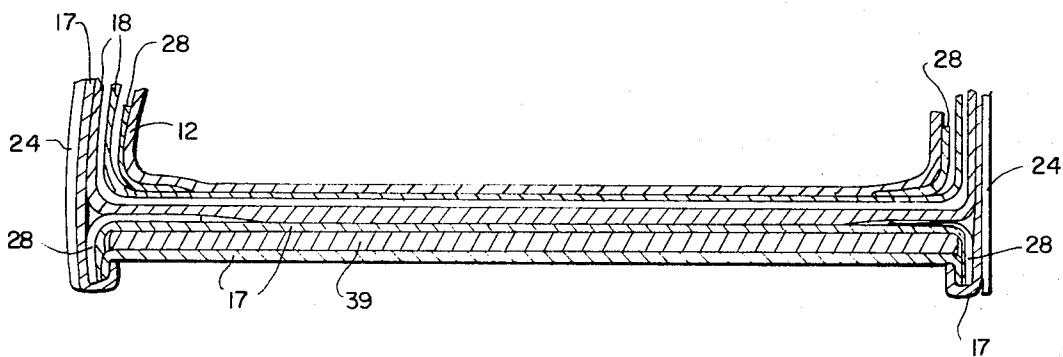
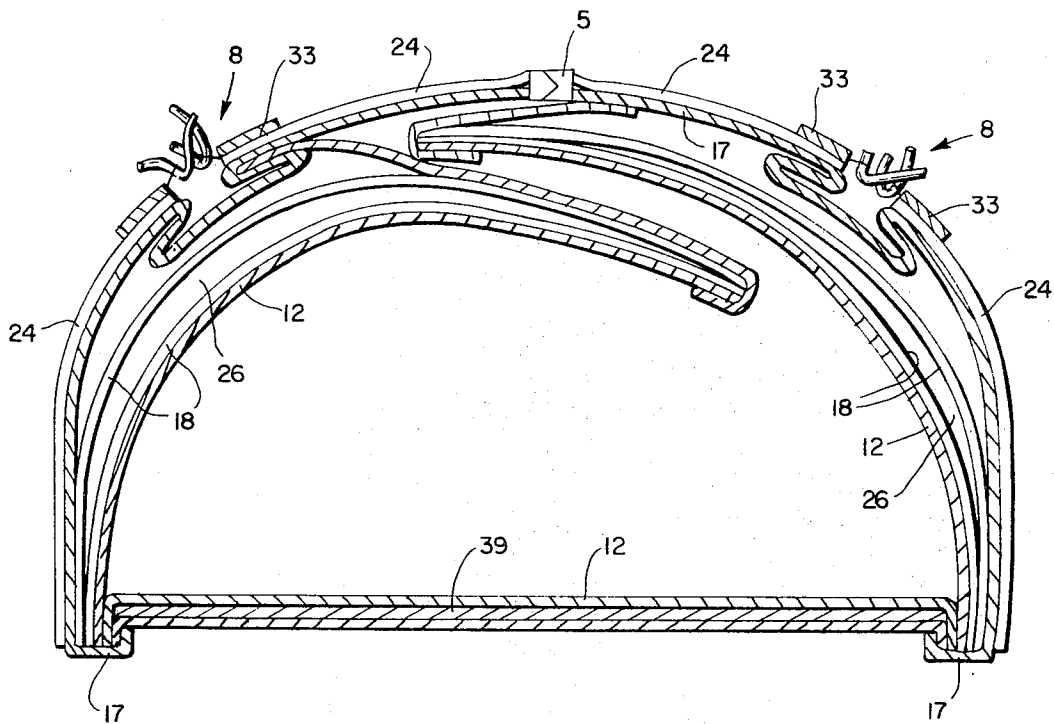
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5 Sheets-Sheet 5



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CARDIOVASCULAR ASSIST DEVICE

BACKGROUND OF THE INVENTION

In the past, various devices have been conceived to compress a single extremity of the human body as a means of treating varicose veins, skin ulcers, flaccid muscles, and the like. None of these devices has been configured and integrated in a manner which is considerate of the total body physiology and body surface area required to effectively mechanically pump blood to reduce the work of the heart of sequentially compressing the arteries and veins of all the extremities, concurrently. It is one thing to apply pressure and suddenly release it on part of an extremity, but to be effective, an external cardiovascular assist device must be sequence pulsated over all extremities, concurrently, with each pulse sequence being keyed by the patient's electrocardiogram to effectively augment the arterial pulse wave in the arterial system. Further, none of the past devices considered the integrated structural means, using textile-type materials, essential in assuring pulsating pressures high enough to increase the aortic pulse pressure while concurrently augmenting arterial and venous blood flow.

SUMMARY

It is the purpose of this invention to describe the means for the structural integration of pressure zones required in an external cardiovascular assist device for reducing the work of the heart and which is easily operable by physicians, nurses, ambulance technicians, and the like.

The structural means for this device are capable of transferring high pressure (up to 10 p.s.i. or more) to the human extremities with a minimum loss of mechanical advantage within the pressurizing materials of the cuff assemblies. The sequence pulsating cuff assemblies encompass, concurrently, all extremities of the human body, extending from the arm pits to enclose the tips of the fingers, and from the groins to enclose the tips of the toes.

Another objective of this invention is to utilize the human physiological responses to eternal mechanical stimulation in the pressure receptors located in the aortic arch and the resulting sequences of autonomic reflex action which, when stimulated by an increase in aortic pressure, reflexively slow the heart rate and reduce the strength of contraction of heart muscle. It is known that if the work of the heart is reduced by 25-30 percent, collateral blood vessels will open within cardiac muscle and will fill with blood during an increase in the resting phase of the cardiac cycle. The establishment of this collateral cardiac circulation can prevent or reduce cardiac infarction which may result from an occlusion of a coronary artery.

High external mechanical pressure is applied, concurrently and sequentially, to all the extremities of the human body in proper sequence with the patient's electrocardiogram and cardiac cycle to raise the aortic pulse pressure after the aortic valves have closed. This mechanical increase in the aortic pulse pressure stimulates the aortic pressure receptors, which in turn reflexively activate the autonomic reflex arch through the autonomic nervous system and thence to the heart to slow the heart rate, reduce the strength of heart muscle contraction, and increase the relaxation phase of each cardiac cycle. Concurrently, with each sequence pulsation of the cuff assemblies there is an increase of venous blood flow back to the heart.

The fully integrated parts will increase the mechanical advantage of cuff assemblies constructed of textile-type materials. The integrated structure described herein has been developed to overcome the stretch (8-19 percent of nominal length) inherent in various textile-type fabric materials when acted upon by high applied pressures. This structural integration is essential and a novel feature of this invention since no industry has as yet produced a non-elastic flexible fabric of a strength which won't stretch under high pressure loads. The failure of past concepts to be effective has been due to a disre-

gard of the losses of mechanical advantage in force transfer which results from a loose unsupported construction and a lack of integration of all component parts in each cuff assembly. A laterally located tube is connected to the restraint material by overlapping tapes so that expansion of the lateral tube on inflation fully stretches the outer restraint material to its maximum stretch to increase the effective transfer of force from the pulsating pressure, inwardly, applied within each pressure bladder zone of each cuff assembly, concurrently, during operation on all extremities of the human body. Positive control of the bladder volume in each pressure compartment of each zone is obtained while maintaining a maximum of applied force from pulsating pressures applied to the arteries and veins within each bladder zone of each cuff assembly, concurrently, during operation on all extremities of the human body. Circumferential structural support is attained adjacent to each pressure zone of each bladder compartment of each cuff assembly, concurrently, during operation on all extremities of the human body.

Means are provided for removing all slack from the restraint cloth by establishing a pre-stretch condition throughout the entire length of each cuff assembly prior to the application of pressure in the laterally located tubes to assure that all restraint materials will be fully pre-stretched, before maximum stretch is accomplished on pressurization of the lateral tubes and prior to sequential pulsation operation on all extremities of the human body. Rapid donning and doffing of each cuff assembly is obtained by the proper structural integration of zippers, Velcro, or similar type closures without affecting the pressure integrity or mechanical efficiency of operation (restraining force pressures up to 10 p.s.i. or more) of each cuff assembly in maintaining the restraint cloth in a fully stretched condition, and maintaining structural and mechanical function during sequential pulsation operation on all extremities of the human body.

Means are provided for introducing high pressures (up to 10 p.s.i. or more) into the bladder compartments for each zone of each cuff assembly, concurrently and sequentially, while maintaining the structural integrity of the adjacent restraint cloth and bladder material during sequential pulsation operation on all extremities of the human body.

The structural arrangement of the bladder compartments of each zone of the cuff assembly includes an overlapping segment of sufficient area to assure that the pressure compartments of each zone fully encompass the circumferential dimensions of all extremities of the human body and that the said extensions of each bladder compartment fully underlie the entire length of the closure device, thereby assuring that all pulsating pressures are equally applied to the entire circumferential area of all extremities of the human body, concurrently, throughout the entire length of each cuff assembly. An independent compartment in each bladder zone of each cuff assembly is provided in a proper relationship with the restraint cloth and of sufficient extent and area to encompass the entire circumference and underlie the entire length of the closure device, while concurrently maintaining a minimum bladder volume, yet assuring a maximum of applied force inwardly to the arteries and veins within each bladder zone of each cuff assembly, concurrently, during operation on all extremities of the human body.

Sequence pulsation pressure is applied concurrently to the hands and feet in proper sequence as a functional zone with each cuff assembly for all extremities of the human body. The slack from the restraint cloth is removed throughout the entire length of each mitten assembly prior to the application of pulsation pressure to assure that all restraint material of the mitten assemblies is fully pre-stretched prior to the application of pressure loads. The pressurizable mittens have positive means for controlling the bladder volume and a means for providing a rigidized integral support structure to the palm, while maintaining a maximum of applied force (up to 10 p.s.i. or more) from pulsating pressure to the arteries and veins of the hand, concurrently, during operation on all upper extremities of the

human body. Rapid donning and doffing of the mittens is provided by a proper structural integration of zipper, Velcro, or similar type closures without affecting the pressure integrity or mechanical efficiency of operation of each mitten of each upper extremity cuff assembly in maintaining the restraint cloth in a pre-stretched condition and maintaining structural and mechanical function during sequence pulsation operation on all upper extremities of the human body. High pressure (up to 10 p.s.i. or more) is introduced into the mitten bladder compartment, concurrently and sequentially, while maintaining the structural integrity of the adjacent restraint cloth and bladder material during sequence pulsation operation on all upper extremities of the human body.

Pressurizable boots are provided with means for removing all slack from the restraint cloth of each boot assembly prior to the application of pressure to assure that all restraint material of said boots is fully prestretched prior to the application of pressure loads. The pressurizable boots include positive means for controlling the bladder volume and a means for providing a rigidized integral support structure to the sole of the foot, while maintaining a maximum of applied force (up to 10 p.s.i. or more) from pulsating pressures applied to the arteries and veins of the foot, concurrently, during operation on all lower extremities of the human body. Rapid donning and doffing of the pressurizable boots is attained by a proper structural integration of zippers, Velcro, or similar type closures without affecting the pressure integrity or mechanical efficiency of operation of each boot of each lower extremity cuff assembly in maintaining the restraint cloth in a pre-stretched condition and maintaining structural and mechanical function during sequence pulsation operation on all the lower extremities of the human body. High pressure (up to 10 p.s.i. or more) is introduced into the boot bladder compartment, concurrently and sequentially, while maintaining the structural integrity of the adjacent restraint cloth and bladder material during sequential pulsation operation on all lower extremities of the human body.

Means, for example a slot or slit, are provided in the cuff assemblies for the upper extremities, structurally re-enforced with restraint tape and located at the proper level of the inner surface of the elbow between pressure zones and within the circumferential restraint structure, to enable the physician to insert cardiac catheters or the like into the arteries or veins of the patient as may be required in the clinical evaluation of the patient without interfering with the structural integrity or the mechanical efficiency and the effective transfer of force from the pulsating pressures within adjacent bladder zones of each cuff assembly, concurrently, during operation on all upper extremities of the human body.

The complete structural integration of all materials in the construction of this cardiovascular assist device will minimize and/or eliminate the effect stretching of textile-type materials has in reducing force transfer as each zone of each cuff assembly is pressurized, and thereby increase the total effective mechanical force applied inwardly to the arteries and veins in each zone, assuring a more effective mechanical pumping pressure acting on the blood in the arteries and veins.

BRIEF DESCRIPTION OF THE DRAWING

Further objects, features and advantages of the present invention will become more clear from the following description of a preferred embodiment shown in the drawing, wherein:

FIG. 1 is a full view of the total cardiovascular assist device applied, concurrently, to all the extremities of the human body;

FIG. 2 is a cross section of a cuff assembly taken on line II—II of FIG. 1, shown in an expanded view to reveal the intimate relationships for the integration of all component parts as arranged around each extremity of the wearer;

FIG. 3 is an enlarged cross-sectional view of the high pressure line connection shown in FIG. 2;

FIG. 4 is an enlarged cross-sectional view taken on line IV—IV of FIG. 1 showing a catheter slot or slit;

FIG. 5 is a cross-sectional view taken on line V—V of FIG. 1 showing the anchoring of the restraint cloth, bladder material and pressure pouch material;

FIG. 6 shows a modification of the FIG. 5 structure;

FIG. 7 shows the means for providing overlap of each pressure zone compartment throughout the length of each cuff assembly in the enlarged cross section taken essentially on the line VII—VII of FIG. 1;

FIG. 8 shows the means for removing all slack material from each cuff assembly before application of pressure in the lateral pressure tube as shown in the enlarged cross section taken essentially on the line VII—VII in FIG. 1, with the lacings closed; FIG. 9 shows the lateral pressure tubes and the inter-lapping tapes that provide the means of maximally stretching the restraint cloth in cross section taken essentially on line IX—IX as seen in FIG. 1;

FIG. 10 shows the essential details of a pressurized boot, which is substantially identical to the pressurized mitten except for the angular relationship between the wrist and ankle;

FIG. 11 is an enlarged cross section of the pressure boot, taken essentially on line XI—XI as seen in FIG. 10; and

FIG. 12 is a partial cross section of a modification of the FIG. 11 structure.

DETAILED DESCRIPTION OF THE INVENTION

As shown in FIG. 1, the cardiovascular assist device of the present invention includes one or more, with four being shown, cuff assemblies 1, each of which is designed to encompass an extremity of the body, for example, the arms and legs. Preferably, each cuff assembly 1 is tubular in shape with its outer extremity end being closed and its opposite end being open. The two cuff assemblies for the two arms of the wearer may be identical or mirror images of each other. Similarly, the two cuff assemblies for the two legs of the wearer may be identical or mirror images of each other. Further, the basic structural features for the leg cuff assemblies and the arm cuff assemblies are correspondingly identical, except that there is an angular relationship at the ankle portion of each leg cuff assembly, because of the correspondingly different angular relationship between the ankle and wrist of the intended wearer. For this reason, only one cuff assembly will be described in detail with the understanding that there is a correspondance between the cuff assemblies.

Each cuff assembly 1 includes a main body portion 2 and a lateral body portion 3, which are cooperatively held with respect to each other by means of interlooping or crossing interconnecting tape connecting members 4. The main body portion 2 is provided with a releasable closure, 5 preferably interengaging, for example Velcro, a zipper, or snaps, which extends from the open end down to the wrist or ankle area, respectively, so that the main body portion may be laid open for easy insertion of the wearer's extremity. The insertion of the extremity is further facilitated by means of reclosable fasteners, for example Velcro, zippers or snaps, 6 (not shown in FIG. 1) on their respective hand or foot mittens 7. The easy donning or doffing of the cuff assemblies by the wearer is particularly enhanced by the above features and important in view of the anticipated convalescent condition of the wearer, for example if the wearer is in a coma resulting from a heart attack. Each mitten 7 is peripherally secured to the adjacent tubular structure of the main body portion and their respective fasteners may or may not be aligned.

Due to the different size extremities to be encountered with different wearers, the slack in the main body portion 2 existing after the fasteners 5 and 6 have been closed is taken up as much as possible manually by means of a lacing 8 extending parallel to and for the full length of each fastener 5, 6. It is important to take up this slack because the interior of each main body portion, including mitten 7, contains an inflatable structure for receiving pulsed air for cardiovascular assist, which pulsing is known per se. More efficient transfer of pulsing pressure and a quicker response time is obtained correspondingly with a tighter fit for each main body portion 2.

Before the pulsing begins, but after the donned cuff assembly has been manually tightened by means of the lacing 8, further slack is mechanically taken out of the main body portions by means of inflating the lateral body portions to apply a force through the connecting tape members 4 to tightly constrict the main body portions about the wearer's extremities. For this purpose, high pressure air inlet nipples 9 are provided for access to the inflatable interior of each lateral body portion 3.

Thereafter, known high pressure air pulsating equipment, which will not be described in detail in this application, is fluid connected by means of the fluid couplings 10 to the inflatable interior of each main body portion 2.

The somewhat schematic representation in FIG. 2 shows the over-all arrangement of the various components in cross section, which components will be shown in more detail in subsequent figures with more detailed explanation. The extremity 11 of the wearer is directly contacted by a suitable pouch material 12 which may be cotton, nylon, or the like. Surrounded by the pouch material 12, there is an overlapping inflatable bag structure 13, which overlaps as shown at its ends 14 beneath the fastener 5. The tape connecting members 4, as seen in FIG. 2, extend from the lacing 8 counterclockwise approximately one-fourth of the way around the main body portion 2, between the main body portion 2 and the lateral body portion 3, clockwise substantially the entire way around the lateral body portion 3, between the main body portion 2 and the lateral body portion 3, and counterclockwise for less than one-fourth of the way around the main body portion 2 to its free terminal end 15 where it is secured to the main body portion 2. Thus, it is seen that the tapes 4 extend between the main body portion 2 and the lateral body portion 3 in the manner of a figure 8 so that inflation of the lateral body portion 3 from its full line position to the dotted line position 16 will exert a considerable force upon the tape connecting members 4, which will be applied around the entire periphery of the main body portion 2 for constricting the main body portion 2 tightly around the extremity 11 of the wearer. To assist in the transfer of these forces and to enclose the bag structure 13, substantially the entire outer surface of the main body portion 2 is provided by an outer layer of restraint material 17, which may be cotton, nylon or the like. Preferably, the restraint material 17 is a woven material with the warp and woof oriented at approximately an angle of 108°.

One of the couplings 10 is shown in detail in FIG. 3, and is substantially identical to the structure of the nipples 9. As shown, the coupling provides fluid access from the exterior through the restraint material 17, and an outer air impermeable wall 18 of the bag structure to the interior of the bag structure for inflating and deflating the bag structure 13, or the inflatable lateral body portion in the case of nipples 9. A threaded stem 19 is provided with an inner flange 20, which one-piece construction may be of metal or like rigid materials. A plurality of angular gaskets 21 are cemented respectively between the flange 20 and the bag material 18, between the bag material 18 and the restraint material 17, and between the restraint material 17 and a nut 22 threaded onto the stem 19. In this manner, the stem 19 is sealingly secured to the assembly and provided with an outer portion for the reception of a complementarily formed pressure nozzle. The nut will clamp the gaskets and assist the cement in this sealing.

As seen in FIG. 1 and in more detail in FIG. 4, an aperture or slot 23 is provided in at least one of the arm cuff assemblies 1 in the region opposite the elbow, which provides access to the wearer's arteries and veins for the insertion or maintenance of cardiac catheters or the like. A physician or technician may insert these catheters while the cuff is on the patient or prior to the cuff assembly being donned for required clinical evaluation of the patient, without interfering with the structural integrity or the mechanical efficiency and effective transfer of force from the pulsating pressures within the adjacent bladder zones of each cuff assembly. If the catheter is inserted into the patient prior to donning of the cuff assembly,

the various tubes may be threaded through the aperture 23 without removal of the catheter during donning of the cuff assembly.

As shown most clearly in FIG. 4, the aperture 23 extends through the outer restraint material 17, both layers of the bag material 18, and the inner pouch material 12. Preferably, cement is provided between each of these layers so that there is a tight sealing arrangement, particularly with respect to the two layers of the bag material 18, which must have an airtight seal. For reinforcement of the aperture, a restraint tape 24 of suitable strong and thick woven material or the like is provided on all sides of the aperture 23, which restraint tape may be approximately three-fourths inches wide and 1¼ inches long. To provide a smooth lining for the aperture 23 between the layers, a binding material 25 extends over the restraint tape 25, lines the aperture 23 and extends under the pouch material 12 as shown on all sides of the aperture 23. The restraint tape 24 and binding material 25 may be cemented and/or stitched to the adjacent layers. A suitable method of assembly would include the cementing and perhaps stitching of the layers 12, 18, 17 and 24, the forming of the aperture 23 with a sharp blade or electric burning tool to approximately a length of 1 inch through all of the layers, and the later cementing and/or stitching of the binding tape 25 around the thus formed aperture to prevent fraying and abrasion.

From a comparison of FIGS. 1 and 5, it is seen that each of the cuff assemblies 1 includes a plurality, particularly 4 excluding the mittens, of independently inflatable bags or bladders 26, which extend circumferentially around the wearer's extremity and are axially spaced with respect to each other. Each of these inflatable bags 26 may be formed by pairs of bag material 18 or by only two sheets of bag material 18 for each cuff assembly by providing a cemented seam 27 between adjacent bags 26. The bags 26 are anchored adjacent their seams 27 to the adjacent layers of restraint material 17 and pouch material 12 by means of a plurality of anchor tabs 28 that are cemented to their respective restraint material 17 or pouch material 12 at one end and cemented at their other end to the adjacent layer of bag material 18. The restraint tape 24 is provided immediately overlying the seams 27 and the anchor tabs 28 to provide additional reinforcement in this important area. Alternately, or in addition, the restraint tapes 24 and anchor tabs 28 may be stitched to their respective adjacent materials.

In FIG. 6, there is shown a construction that could be used instead of a construction shown in FIG. 5 to form the plurality of separate bags 26'. With this modification, the restraint tape 24', the restraint material 17', the bag material 18', the pouch material 12', and an over-tape for reinforcement 29 are stitched and/or cemented together. The construction shown in FIGS. 5 & 6 are necessary to form the separate pressure zones or bags, for circumferential alignment, and to assure proper bladder or bag positioning and structural support. Thus, positive volume control for each pressure zone is obtained by the complete integration of all components as described above. This is accomplished by securely anchoring all layers of materials one into the other and is essential in preventing lateral or longitudinal displacement of the pressure zones or bags of all cuff assemblies on the extremities of the wearer as well as to assure the maximum inward direction of mechanical forces during sequence pulsation operation.

FIG. 7 shows in greater detail some of the structural features that were somewhat schematically shown in FIG. 2 and on a larger scale. The fastener 5, which is shown as a zipper, has its connecting tapes 29 stitched or otherwise secured to the adjacent restraint material 17 and pouch material 12. Furthermore, the stitching will secure the ends of the circumferentially extending restraint tapes 24 and extend along the outermost longitudinally extending restraint tapes 24 for additional reinforcement. It is seen that the pouch material 12 extends from where it is stitched as mentioned above to the left of the fastener 5, as seen in FIG. 7, downwardly and to the right to end 30 where it is folded back around the sealed edges of the bag material 18 to overlie and protect these edges,

where it is stitched or otherwise secured. The same sheet of material 12 may extend back towards the left or an additional sheet of pouch material 12 may be used as shown, which would also be secured at end 30. Similarly, the other terminal edge of the pouch material 12 extends from where it is stitched to the right-hand tape 29 of the fastener 5 downwardly and to the right to point 31 where it is stitched or secured to an additional sheet of pouch material 12 that extends back towards the left and over its bag material 18. To assure the proper positioning of the last-mentioned two sheets of pouch material 12, an anchor tab 28 is secured between the pouch material 12 at point 31 and the adjacent sheet of bag material 18. At securement point 32, the structure is substantially a mirror image of the structure recited at end 30, with a single sheet of pouch material 12 extending circumferentially around the extremity of the wearer from edge 32 to end 30.

Also, the lacings 8 are shown in more detail in FIG. 7, wherein the two parallel lacing tapes 33 are secured by stitching or the like on the right to the restraint material 17, with the interposition of the terminal ends of the circumferentially extending restraint tapes 24, and on the left to the restraint material 17 with the interposition of the terminal ends of the tape connecting members 4. Each of the lacing tapes 33 is provided on its edge facing the other lacing tape with a plurality of loops 34, through which extend the laces 35, in a known manner so that by adjustment of the laces 35, the lacing tapes 34 may be drawn together for constricting the restraint material 17 about the wearer's extremity. Since the restraint material 17 extends as one piece beneath the lacings 8, there will be formed slack restraint material at 36 when the lacing tapes 34 are drawn together, so that the cuff assemblies are sealed at the lacings.

The structure shown in FIG. 7 provides an overlapping of the pressure bags beneath the fastener 5, which will not only facilitate donning and doffing of the cuff assemblies 1, but will also assure a continuous overlap of all pressure zones throughout the entire length of each cuff assembly for all extremities and provides for a uniform application of pressure to the surfaces of all extremities during sequence pulsation operation. Structural integrity is further maintained by means of circumferentially extending restraint tapes 24 and the longitudinally extending restraint tapes 24. Direct action and quick response of the pressure pulsations within the pressure zones is assured by the manual tensioning of the restraint cloth 17 through adjusting the laces 35 to draw the lacing tapes 33 toward each other, which will also maintain a continuous tension on the restraint cloth circumferentially and longitudinally to thereby establish a pre-stretched condition for the entire length of the cuff assemblies. FIG. 8 illustrates the manner in which the restraint material slacked at 36 will fold tightly under the pressure exerted by the tensioned cuff assembly against the wearer's extremity during tightening the laces 35.

After the laces 35 have been tightened as mentioned above to the construction of FIG. 8, the lateral body portions 3 will be inflated to react through the tape connecting members 4 for further constricting the main body portion 2 about the wearer's extremity. This relationship is shown particularly in FIG. 9. The lateral body portion 3 has a longitudinally extending restraint tape 24, which is stitched to the outer tubular restraint material 37 to securely hold the tape connecting members 4 in their proper spacing longitudinally of each other and to provide structural integrity for the lateral body portion. Within each lateral body portion 3, there is a single inflatable tube 38, which extends the entire longitudinal length of the lateral body portion within the tube of restraint material 37. It is thus seen by inflating the tube 38, the restraint material 37 will expand to tension all of the tape connecting members 4 and pull additional lengths of tape connecting members 4 from the main body portion 2 to further constrict the main body portion 2 about the wearer's extremity. The size of the inflatable tube 38 is chosen such that its circumference is approximately one-fifth the circumference of the main body portion 2. The functional length of the tape connecting members

4 is selected such that maximum expansion of the lateral pressure inflatable tube 38 will apply maximum stretching force, circumferentially, through the diametrically opposed integrated anchor of points for the terminal ends of the tape connecting members 4 on the main body portion 2. Structural reinforcement of the anchoring points is provided by the restraint tapes 24 extending for the entire longitudinal length of the lateral body portion 3 along the middles of the tape connecting members 4 and the main body portion 2 along the terminal ends of the tape connecting members 4. As previously mentioned, each inflatable tube 38 has access to its inflatable interior by means of a nipple 9 shown in FIG. 1. In this manner, structural integration and support of all component parts of each cuff assembly is provided, by interconnection of all restraint material 17, restraint tapes 24, bladder or bag material 18, pouch material 12, fastener 5, tape connecting members 4, lacings 8, and the inflatable tube 38.

A mitten, particularly a foot mitten, is shown in FIG. 10, with like numerals applied to structural elements that are identical to previously described structural elements. It is understood that the hand and foot mittens are substantially identical, except for the correspondingly angular difference between the ankle and wrist portions thereof. However, it is seen from FIG. 10 that two lacings 8 are provided, one on each side of the fastener 5, instead of only one lacing as previously described with respect to the main body portions 2. Each mitten is secured to the terminal end of its respective main body portion 2, to close the same.

Specific details of the mittens are shown in FIG. 11, with like numerals being used as mentioned above. The upper portion of FIG. 11 is substantially identical to the structure shown in FIG. 7 with respect to the details of the fastener 5, lacings 8, and the overlapping of pouch material 12 and bag material 18 beneath the fastener 5, except that in FIG. 11, two lacings are provided. Therefore, for details of the various structural components, reference is made to the description with respect to FIG. 7, which is equally applicable with respect to identical structural components as shown by like numerals.

Each mitten is provided with a hard sole or palm portion 39, as the case may be respectively for the foot or hand. This hard sole 39 is covered on each face by means of pouch material 12. The hard sole 39 is constructed of metal, or similar rigid material, and of a sufficient strength to resist bending during sequence pulsation and thereby increase the effectiveness of the sequence pulsating bladder 26. Fluid access to the bag 26 is provided by means of a fluid coupling (not shown in FIG. 11) which is identical to the fluid coupling shown in FIG. 3. It is seen that all of the terminal ends of the sheet material, except for the restraint tapes 24, are assembled at the edges of the sole 39 where they are sealed by cement and otherwise tightly secured together, with the outer layer of restraint material 17 being folded around the edge portions to prevent fraying and abrasion.

A further modification of the sole structure is shown in FIG. 12. In this modification, the bag material 18 extends completely across the rigid sole 39 and is connected respectively by anchor tabs 28 to the inner pouch material 12 and the outer restraint material 17.

OPERATION

It is known physiologically that a pressure gradient exists, inwardly whenever mechanical pressure is applied to the surface of the human body. Therefore, it is an important feature of the present invention to provide the means for introducing high pressure (up to 10 p.s.i. or more) into all pressure zones or individual pressure bags of the main body portions and inflatable tubes of the lateral body portions to assure that adequate mechanical forces are obtained during the operation of the cardiovascular assist device. Each cuff assembly is so constructed for each body extremity so that the pulsating forces tending to increase the circumferential size and longitudinal length by stretch of the fabric-type materials of each

pressure zone compartment will be optimally balanced, one against the other, when pulsating pressures are applied. In this manner, the maximum restraint characteristics inherent in the weave of the warp and woof of the fabrics, due to the friction of interlocking threads within the fabrics, are utilized to resist further stretching, when pulsating pressure is applied, by first removing all slack within the restraint cloth by manually tightening lacings to establish a prestretched condition, and thereafter by mechanically pre-stressing all of the fabrics with the introduction of high pressure fluid within the lateral body portion inflatable tubes. Maximum stretch, pre-setting the restraint cloth is then obtained through the combined efforts of the manual lacing and the pressurized lateral body portions that apply tension to the main body portions through the tape connecting members.

In use of the cardiovascular assist device for encompassing all extremities of the human body concurrently, the manipulative procedures are as follows. The main body portions with their pressure mittens are donned first with the fasteners 5 open and the lacings 8 expanded. Each hand and foot is appropriately positioned against the hard palm or sole support structure of the respective mittens. Next, the pressure compartment flaps are carefully overlapped beneath each fastener, which fastener is thereafter joined and closed. Afterward, the laces are adjusted to manually take up any slack within the restraint cloth and pre-tension the restraint cloth for each main body portion, including mittens. The wrist flaps and ankle flaps of adjacent inflatable bags are configured such that the arm and leg cuff assemblies, respectively, will overlap the flaps by approximately 3 or 4 inches. At appropriate points within the preceding donning procedure, any catheters that were previously inserted within the patient's arteries or veins adjacent the elbow portion of his extremity, are fed through the aperture or slot and the corresponding cuff assembly, or after donning, the appropriate catheter is inserted.

Thereafter, the inflatable tube of each lateral body portion is connected by a suitable pressure coupling to a constant pressure source of high pressure fluid to inflate the lateral body portions and correspondingly constrict the main body portions.

Each separate pressure zone or bag of each cuff assembly is independently connected by means of its fluid coupling to the mechanical sequence pulsating unit (not shown, but conventional). Suitable electrodes 40 are secured to the wearer in a known manner as shown in FIG. 1 to obtain the electrocardiographic signals required to control and phase the pulsating sequence with each cardiac cycle of the patient. The total cardiovascular assist device applied to all extremities of the human body is then ready for sequence pulsation operation. The entire sequence pulsation, simultaneously for all ends or extremities, takes place within the pressure bladders of each zone concurrently in each cuff assembly during the time of one heartbeat, at which time pressure is released and the zonal sequence repeated with the next heartbeat.

While several modifications of the preferred embodiment of the present invention have been specifically illustrated and described, it is understood according to the broader principles of the present invention many modifications, embodiments and variations are contemplated.

I claim:

1. A cardiovascular assist device, comprising: a main body portion adapted to be assembled around the extremity of a patient, and having a longitudinal extent with opposite ends; fluid expandable bladder means within said main body portion for exerting an inward pulsating pressure to the patient corresponding to pulsating fluid pressure supplied to the bladder means; separate fluid expandable chamber means adjacent to and parallel to the longitudinal extent of said main body portion for expansion in response to fluid pressure supplied thereto to constrict said bladder means around the extremity of the patient, closure means attached to at least one end of said longitudinal extent of said main body portion, said closure means including a rigid plate longitudinally extending along

one side and adapted to receive the sole or palm of the patient, and bladder means extending around the entire circumference of the closure means, said bladder means being positioned inwardly of said rigid plate.

2. The device of claim 1, wherein said main body portion is adapted to extend substantially the full longitudinal length of the patient's corresponding extremity; said expandable chamber means extending substantially the entire longitudinal length of said main body portion.

3. The device of claim 1, including a plurality of separate connecting tapes, each secured at their opposite ends to said main body portion, to extend from one end partially around said main body portion, between said main body portion and said expandable chamber, reversely around said expandable chamber, between said main body portion and said expandable chamber and partially around said main body portion to its other end.

4. The device of claim 1, including releasable fastener means extending for substantially the full length of said main body portion to permit opening and closing of said main body portion along one entire longitudinal side for donning and doffing by the patient.

5. The device of claim 1, wherein said main body portion includes lacing means extending for substantially its full longitudinal length to permit manual constriction and expansion of said main body portion bladder means.

6. The device of claim 1, including a plurality of said cuff assemblies adapted to be attached to each extremity of the patient.

7. The device of claim 1, wherein said main body portion has an outer layer of restraint material being substantially more dimensionally stable than said bladder means and extending for the full longitudinal length and full circumference of said main body portion; and a pouch material forming the inside surface of said main body portion and extending for the full longitudinal length and circumference of said main body portion.

8. The device of claim 7, including a plurality of restraint tapes longitudinally spaced with respect to each other and extending circumferentially around said main body portion; and a plurality of additional restraint tapes circumferentially spaced from each other and extending for the full longitudinal length of said main body portion.

9. The device of claim 1, including slot means permitting the passage of a catheter radially through said main body portion to the arm area of the patient opposite from the elbow; said slot means being a narrow longitudinally aligned slot extending completely through said main body portion.

10. The device of claim 9, including reinforcing means extending externally completely around said slot; and binding means extending completely externally around said slot, along all the inner walls of said slot and continuously internally around said slot.

11. The device of claim 1, wherein said closure means includes a mitten-type body forming a closure for one end of said body.

12. The device of claim 11, including fluid expandable bladder means extending at least partially circumferentially around said mitten and longitudinally thereof for exerting an inward pulsating pressure to the patient in response to being supplied pulsating fluid under pressure.

13. The device of claim 11, wherein said mitten has releasable fastener means extending for substantially its full longitudinal length.

14. The device of claim 13, wherein said mitten includes lacing means extending for substantially the full longitudinal length of said mitten and on each side of said releasable fastener means, for manually constricting said mitten in the circumferential direction.

15. The device of claim 11, wherein said mitten includes a rigid plate longitudinally extending along one side and adapted to receive the sole or palm of the patient.

16. The device of claim 1, wherein said main body portion bladder means includes a plurality of separate inflatable bags longitudinally spaced with respect to each other and each circumferentially extending around the full circumference of the main body portion.

17. The device of claim 16, wherein each of said inflatable bags has opposed overlapping ends, with the corresponding ends of all inflatable bags being longitudinally aligned; and releasable fastener means for completely opening one longitudinal side of said main body portion radially opposite from said overlapping ends of said inflatable bags.

18. The device of claim 16, wherein each inflatable bag includes a separate fluid coupling; and said expandable chamber means including a separate fluid coupling.

19. The device of claim 16, including a plurality of longitudinally spaced and circumferentially extending restraint tapes, with each tape longitudinally alternating with said inflatable bags.

20. The device of claim 16, including restraint material circumferentially extending completely around and longitudinally along said main body portion to form its outer surface; pouch material circumferentially extending around and longitudinally along said main body portion to form its inner surface; a plurality of restraint tapes, each extending circumferentially along the outer surface of said restraint material immediately radially opposite the division between longitudinally adjacent inflatable bags; a plurality of binding tapes circumferentially extending around the inner surface of said pouch material directly radially opposite the division between

longitudinally adjacent inflatable bags; each of said inflatable bags being formed of two resilient sheets; respective ones of said restraint tapes, said restraint material, said resilient sheets, said pouch material, and respective ones of said binding tapes being circumferentially bonded one to the other at least along a common radially extending plane.

21. The device of claim 16, wherein each of said inflatable bags is constructed of only two resilient sheets bonded together along circumferential lines forming the division between longitudinally adjacent bags and together along two longitudinal lines forming said overlapping ends.

22. The device of claim 21, including restraint material circumferentially and longitudinally surrounding and forming the outer layer of said main body portion; a plurality of anchor tabs, each having one end secured to the inner surface of said restraint material and an opposite end secured to a respective one of said inflatable bags; a pouch material circumferentially extending and longitudinally extending to form the inner surface of said main body portion; a plurality of anchor tabs each having one end secured to a respective one of said inflatable bags and an opposite end secured to said pouch material; all of said anchor tabs being located immediately radially of the division between longitudinally adjacent inflatable bags.

23. The device of claim 22, including a restraint tape circumferentially extending around said main body portion radially opposite each division between longitudinally adjacent inflatable bags.

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