Feb. 11, 1969 R. H. BALL 3,426,744

HEART PUMP CANNULA

Filed Feb. 27, 1964

FIG. 1

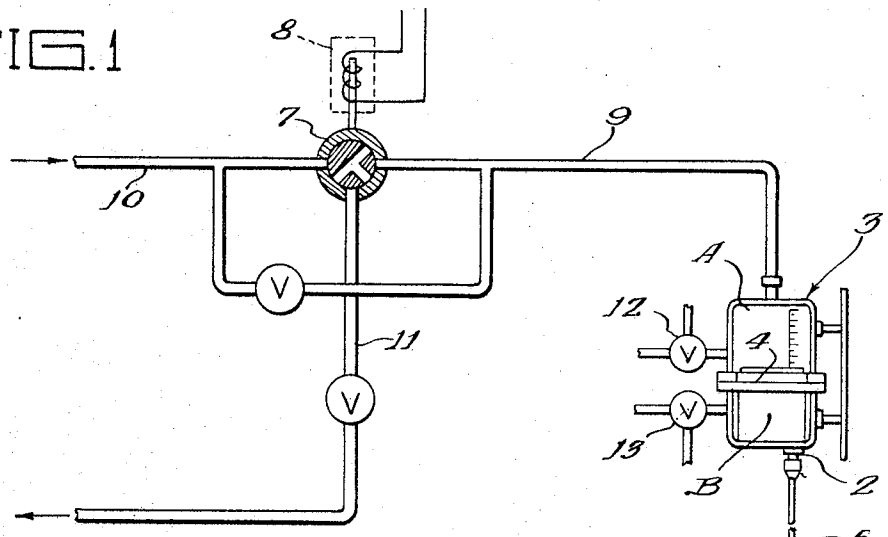


FIG. 4

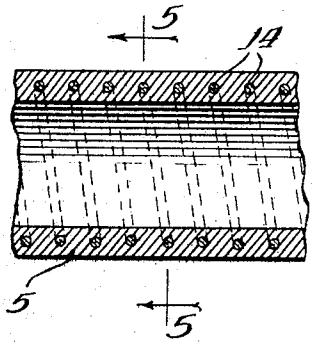


FIG. 6

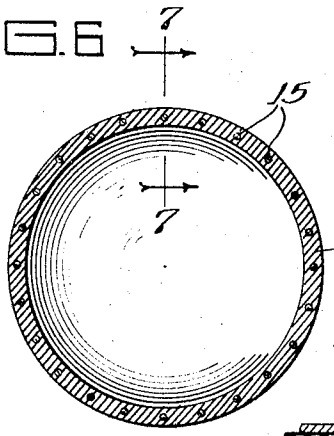


FIG. 7

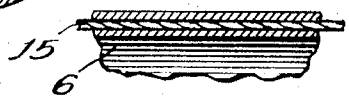


FIG. 3

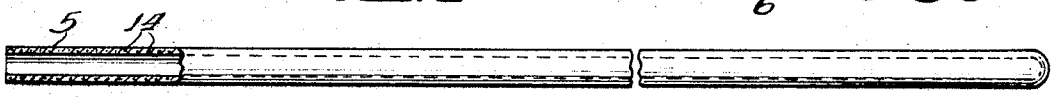


FIG. 2

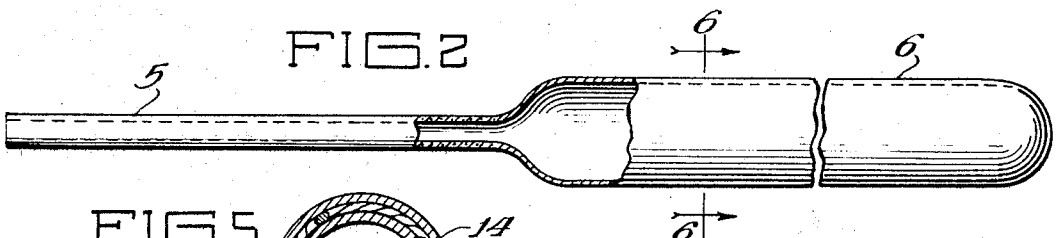
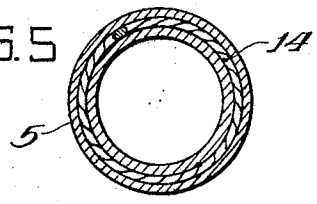


FIG. 5



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3,426,744

HEART PUMP CANNULA

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U.S. Cl. 128—1 1 Claim
Int. Cl. A61h 31/00; A61m 5/14, 29/02

ABSTRACT OF THE DISCLOSURE

A heart pump cannula is provided which includes a closed end radially inflatable tubular portion connected to a reinforced, noninflatable tubular portion. The closed end inflatable portion is provided with longitudinal reinforcement cords for the purpose of preventing longitudinal expansion of the inflatable portion, while the noninflatable portion is provided with a reinforcing cord sleeve which prevents any expansion thereof. In use, the cannula is inserted through the femoral artery until the inflatable portion is within the descending aorta. The cannula is then connected to a reciprocating heart pump system which alternately pumps and withdraws fluid from the inflation portion thereof, thereby causing a pulsating action of the inflatable portion within the descending aorta of the body, radial expansion of the cannula within the femoral artery being prevented.

This invention relates to an apparatus for assisting the insufficient natural heart action of a cardiac patient.

In one such apparatus a cannula is inserted into the patient's aorta and is suitably controlled during both the systole and diastole phase in timed relation to the patient's natural heart beat. It assists or even replaces the heart action in filling the aorta while emptying the related left centricle of the heart. Thereafter and during the systolic phase of the cycle of heart operation, the pumping apparatus discharges fresh arterial blood from the aorta into the arterial tree, by the application of energy from a source external to the patient. Heart assist systems of this type are referred to in the art as arterio-arterial systems. An exemplary system of this type is generally described in the copending application of Merrill G. Chesnut and Richard H. Ball, and assigned to the assignee of the present invention, Ser. No. 347,500, filed Feb. 26, 1964.

In heart pumping systems in which the pumping cannula or membrane is inserted directly into the arterial tree, problems arise in the construction of such a cannula which are not present in the more conventional complete or partial heart pumping systems, i.e. systems which divert the flow of blood from the body through an external pump and thereafter return the blood to the body. For example, the deflated size of the pumping membrane in relation to its inflated size is extremely critical; and the membrane is limited in size by the particular vascular passage in which it is inserted. In bypass systems, the pumping membrane is situated away from the body and has no size limitations.

While it is desirable to provide a cannula which is of sufficiently small diameter to be easily inserted into the vascular system, it is also necessary that the cannula be expandable to a sufficient diameter to provide efficient pumping action while within the circulatory system. Here again, bypass systems have no such limitation on the size to which the pumping member may be expanded. The presently disclosed cannula is usually inserted within the femoral artery and gently urged into the descending aorta. The pumping force of this type of system is in part

dependent upon the relative displacement of the cannula within the aorta from its deflated to its inflated size.

A further problem in the intracorporeal pumping system is that of cavitation and trauma of the blood as a result of the artificial pumping action thereon, which may cause hemolysis.

It is therefore an object of the present invention to provide solutions to the above mentioned and other problems in this art. More specifically the present device includes an inflatable membrane for insertion into the arterial tree of the patient. When deflated, the membrane or cannula is approximately ⅛ of an inch in diameter, thereby providing for and facilitating insertion into the femoral artery. The cannula, which has a closed end, is inflatable only near the closed end so that the portion thereof adjacent the pump and lying within the smaller arteries will not expand and rupture these arteries.

Another object of the present invention is to provide means for limiting the elongation of the cannula or tube during the period of expansion or inflation thereof.

A further object of the present invention is to provide means for limiting the radial expansion of the cannula or membrane over a portion thereof.

Yet another object of the present invention is to provide an inflatable cannula for insertion into the circulatory system which is made from a fully elastic material. The prevention of wrinkling of the cannula by using an elastic rather than an inelastic material results in the reduction of blood cavitation and trauma.

Other objects and advantages in part will become readily apparent from the following detailed description taken in connection with the accompanying drawings, in which:

FIGURE 1 is a partial schematic view of a portion of the mechanical-hydraulic system and apparatus of my invention for heart assisting;

FIGURE 2 is an enlarged plan view of the cannula when expanded, partly in cross section;

FIGURE 3 is an enlarged view of the cannula when deflated;

FIGURE 4 is an enlarged view of the portion of the cannula shown in cross section in FIGURE 3;

FIGURE 5 is a cross section taken along lines 5—5 of FIGURE 4;

FIGURE 6 is a cross section of the inflated cannula taken along line 6—6 of FIGURE 2; and

FIGURE 7 is an enlarged cross section taken along line 7—7 of FIGURE 6.

While an illustrative embodiment of the invention is shown in the drawings and will be described in detail herein, the invention is susceptible of embodiment in many different forms and it should be understood that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the invention to the embodiment illustrated. The scope of the invention will be pointed out in the appended claim.

Throughout the several views of the drawings like reference characters denote like parts.

In order to gain a more ready and thorough understanding of my invention, it may be noted here that situations are frequently encountered in the treatment of heart patients when the patient's heart action is simply not sufficient to supply the patient's bodily needs. This is so regardless of the reason therefor. Usually, however, this is attributed to a lack of sufficient muscular activity within the heart itself. Frequently the situation is encountered that while the diastolic action of the heart will bring a volume of blood into the left ventricle of the heart sufficient to supply bodily needs, this ventricle will not fully empty into the aorta. Or, should the ventricle fill the aorta with arterial blood, the systolic action of the

heart is not thereafter sufficient in itself to discharge all the blood content of the aorta into the arterial tree. Blood backs up, stagnates, and seriously impairs bodily function. Conveniently, we term this weakness of heart action, heart failure. Heart failure may be so complete that, for all practical purposes, there is no natural action on the part of the patient. In such situations, auxiliary equipment must completely take over the natural heart function.

Turning now to a description of my invention, attention is directed to the several views of the drawing. FIGURE 1, in schematic form, shows the mechanical and hydraulic components for inflating and deflating a cannula **1**. The cannula **1** is connected to the nipple **2** of the pump **3**. The pump **3** is of the flexible diaphragm type, and includes chambers A and B, separated by the flexible diaphragm **4**. Thus, the chamber B, the constricted portion **5** of the cannula, and the inflatable portion **6** of the cannula, form a closed hydraulic circuit. The fluid within this closed system is of the type that is compatible with blood, such as "Dextran" or a saline solution. Even though the possibility of leakage in this system is remote, as opposed to a conventional bypass system where leakage is a serious problem, this precautionary measure is desirable.

A three-way control valve **7** supplies fluid to the pump **3** through feed line **9**. Line **10**, connected to the three-way hydraulic valve **7** at one end, is connected at the other to a source of fluid pressure. Line **11** is connected at one end to the three-way hydraulic valve **7** and at the other to a source of vacuum. Solenoid **8** actuates the hydraulic valve to connect either the vacuum line or the pressure line to the pump feed line **9**, thereby subjecting chamber A to either pressure or exhaust in simulating the heart action.

For filling the fluid chamber A to the proper level, a valve **12** is provided. Since it is necessary from time to time to fill the chamber B with a Dextran solution, a valve **13** is provided and connected to the chamber so that it may be filled to the proper level.

The operation of the over-all system is as follows. The cannula **1** is inserted into the femoral artery of the patient and gently forced up into the descending aorta. A pump control assembly (not shown) controls the operation of solenoid **8** in timed relation to the natural rhythm of the patient's heart. Now, assuming the time sequence to be such that the first part of the systolic beat of the heart takes place, then the heart valve will open from the left ventricle to the aorta. At the same time, the membrane or cannula **1** is suddenly collapsed. This is effected by connecting the three-way hydraulic valve **7** to vacuum line **11** during heart valve opening. This action assists in drawing blood from the left ventricle into the space made available in the aorta, filling the same. Upon completion of this phase and with the aorta space substantially filled, then with the natural heart action, the valve closes between ventricle and aorta. The pressure necessary to supply the arterial tree comes from inflation of the membrane, as noted hereinafter.

At or about the time of heart valve closure, the three-way valve **7** connects the compressed fluid supply through line **10** to the inlet of the diaphragm pump **3**. During this power phase of the heart cycle, the diaphragm **4**, as shown in FIGURE 1, is forced downwardly and compresses the "Dextran" fluid in chamber B and forces it out through line **5** into the inflatable portion of the cannula. This expansion of the cannula, within the aorta, forces the blood supply already in the descending aorta into the arterial tree, thereby relieving the heart of the normal systolic back pressure. The operation of the device is then repeated under the next or diastolic cycle of the natural heart.

Referring now to FIGURE 2, where the cannula or membrane **1** is shown in its inflated position, the cannula **1** is made of an elastic material, preferably latex or gum rubber. Embedded within the left hand portion of the cannula or tube **1**, as viewed in FIGURES 4 and 5, is a sleeve **14** made of a synthetic material such as rayon or nylon cord. The over-all length of the cannula or membrane is usually about 17 inches. The sleeve **14** preferably extends for a length of 9 inches from the left hand side of the cannula, as view in FIGURE 2. This prevents the left hand side of the cannula from expanding while at the same time allowing the right hand side to inflate when subjected to pressure from the pump **3**. However, the same result may be obtained by using other means for restraining the open end of the cannula. For example, the left hand portion of the cannula may be cured to a harder consistency than the closed end to prevent expansion of the portion adjacent the open end.

In order to prevent longitudinal expansion of the cannula or tube **1** during inflation, nylon or other synthetic cords **15** are embedded within and along the entire length of the cannula. These cords run lengthwise of the cannula or parallel to the central axis thereof, as shown in FIGURES 6 and 7. This allows the cannula portion **6** to expand radially but limits the over-all longitudinal expansion thereof.

In FIGURE 3, the cannula or tube **1** is shown in its deflated position. It should be noted that when the cannula is deflated, it maintains its cylindrical shape because of its elastic rubber composition and does not wrinkle or twist when evacuated. This fully elastic contraction of the cannula minimizes the cavitation and trauma of the blood when the cannula is collapsed within the aorta during the cycle in which blood is flowing into the aorta from the ventricle.

I claim:

1. An inflatable member for insertion into the circulatory system to assist the natural heart action, adapted to be connected to a heart pumping system including a reciprocating pump for alternately pumping and withdrawing a blood compatible fluid to and from said inflatable member, said inflatable member comprising a cylindrical elastic inflatable membrane having a closed end for insertion through the femoral artery and into the descending aorta of a patient, said inflatable membrane being made from a substantially uniform elastic material, whereby said membrane will expand and contract without losing its cylindrical shape, said membrane having an open end adapted for connection to the reciprocating pump, said membrane having synthetic cords embedded therein and extending longitudinally thereof over substantially its entire length for preventing longitudinal expansion of said membrane over substantially its entire length, said membrane having a synthetic cord sleeve embedded therein from the open end thereof for a substantial distance toward the closed end thereof, said synthetic cord sleeve extending through that portion of the membrane which resides, when in use, inside the femoral artery, to prevent the radial expansion of said membrane within the femoral artery and to permit the membrane to expand and contract within the descending aorta only.

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DALTON L. TRULUCK, *Primary Examiner.*

U.S. Cl. X.R.

128—214, 344, 348