Compendium of Technical and Scientific Information for the

HEMOPUMP® Temporary Cardiac Assist System

Caution–INVESTIGATIONAL DEVICE,
LIMITED BY FEDERAL LAW
TO INVESTIGATIONAL USE.

Johnson & Johnson
INTERVENTIONAL SYSTEMS

INTRODUCTION

Cardiogenic shock is a syndrome associated with impaired left ventricular (LV) performance, resulting in an inability of the heart to fulfill the metabolic requirements of vital organs. Severe cardiogenic shock is responsible for the vast majority of in-hospital deaths following acute myocardial infarction (MI). In addition to acute MI, other conditions that can precipitate cardiogenic shock include dilated congestive cardiomyopathies, difficulty weaning from cardiopulmonary bypass utilized during open-heart surgery, and low output syndromes in the early days after surgery.

Among patients with elevated filling pressures and drastically reduced cardiac index, the in-hospital mortality rate is greater than 90%. In all, approximately 150,000 patients in the United States die every year from complications associated with cardiogenic shock states.

The HEMOPUMP Temporary Cardiac Assist System is an investigational device based on a new design concept. The HEMOPUMP System is intended to assume up to 80% of the workload of the resting heart for up to seven days, thus giving the heart in cardiogenic shock the opportunity to rest and recover normal function.

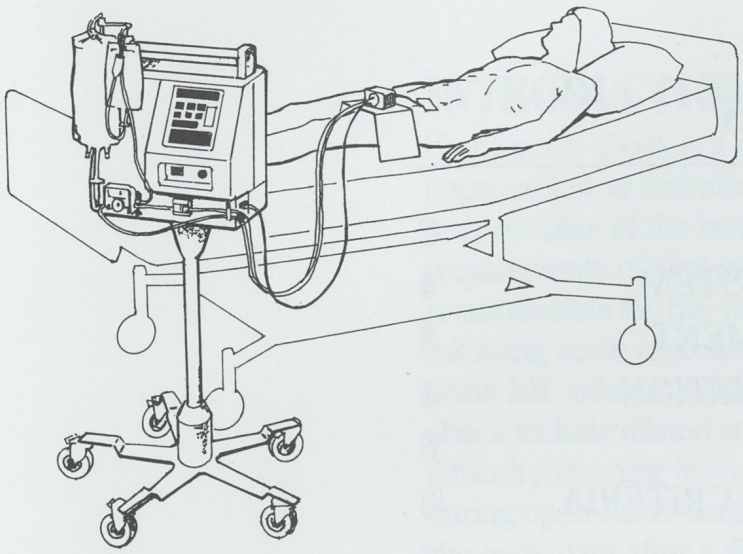
This compendium will describe the HEMOPUMP System, present its proposed indications, contraindications and potential adverse effects, and discuss the animal and human data available thus far.

TABLE OF CONTENTS

COMPONENTS OF SYSTEM

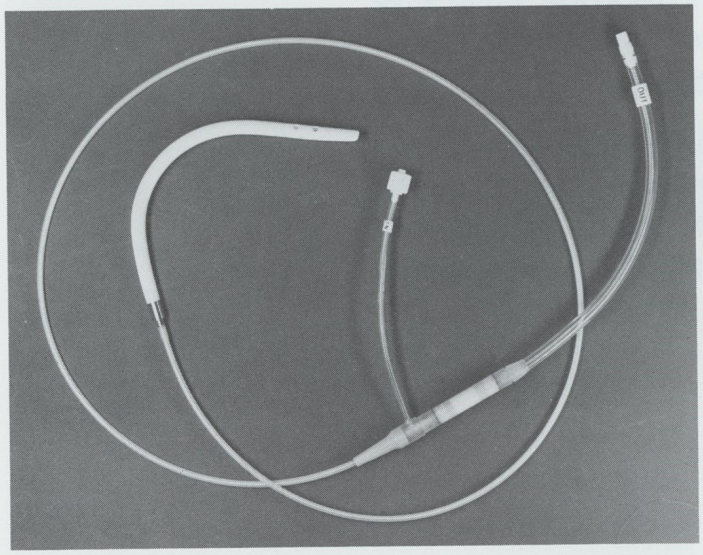
The HEMOPUMP System (Figure 1), which will be distributed by Johnson & Johnson Interventional Systems, Inc., consists of the following:

Figure 1



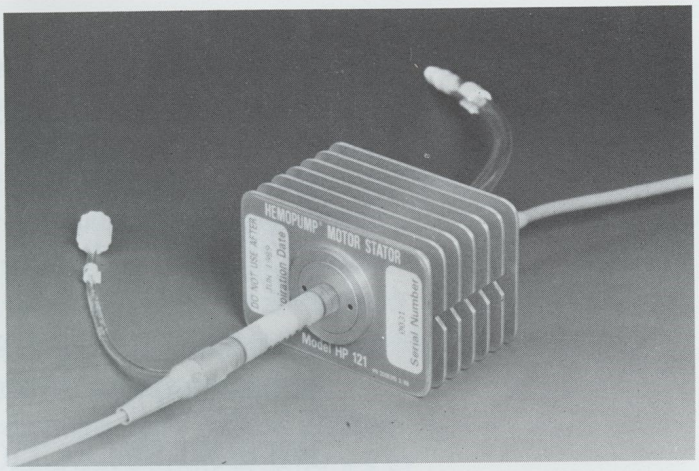
– The pump assembly (Figure 2) is the indwelling device that provides direct circulatory assistance. About the size of a pencil eraser, the pump assembly is made of stainless steel, and is disposable. The curved, silicone rubber inflow cannula, which is 26 cm long and 7 mm in diameter, is reinforced with a coil spring to maintain flexibility and prevent kinking, and has a flexible, beveled tip. A pump assembly with a straight, 9.5 cm cannula, for transthoracic insertion, is also available.

Figure 2



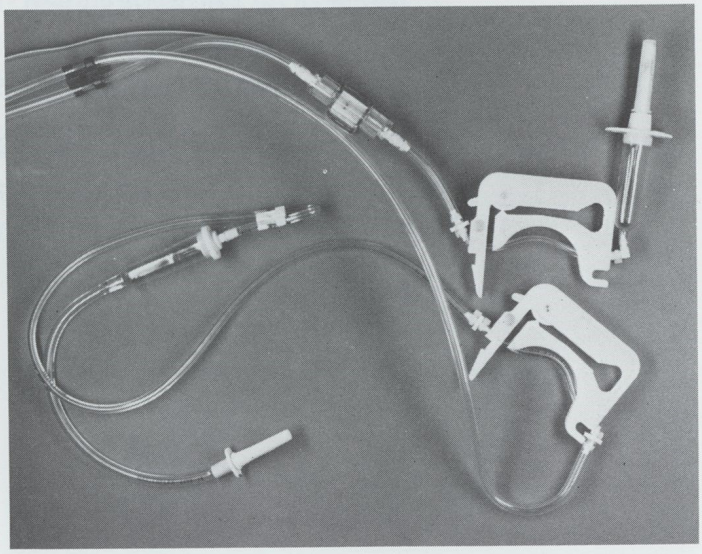
– The integral pump/cannula assembly is propelled by a flexible drive shaft, which is coupled to a magnet in the motor stator outside the patient's body (Figure 3). Because this interface is magnetic, the system is entirely closed. No seals are required, and there is no contact of blood with the drive motor.

Figure 3



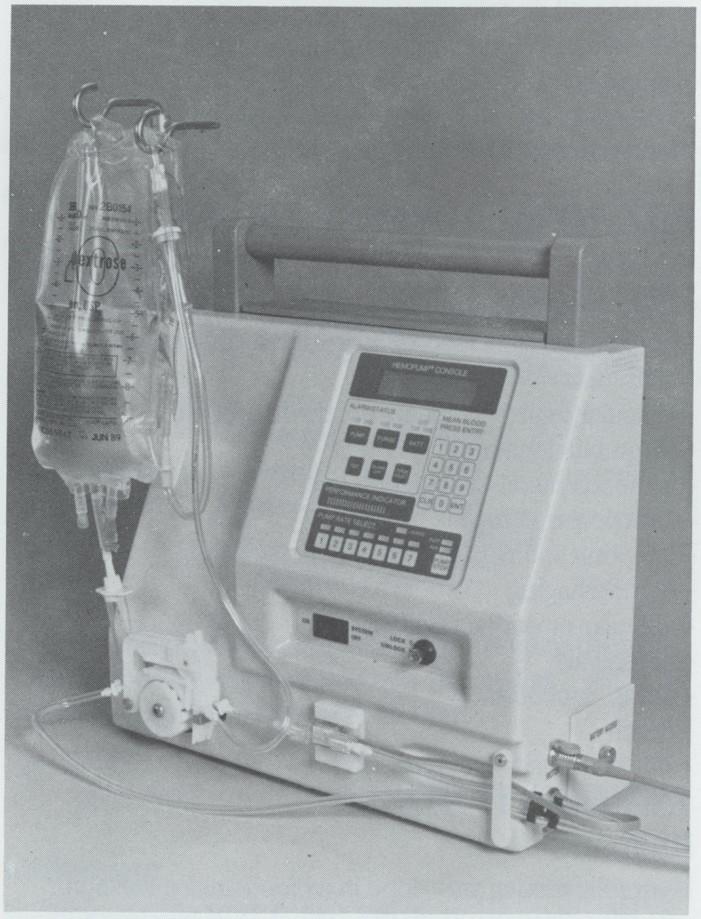
– The purge set assembly (Figures 4 and 5) provides hydrodynamic lubrication for the pump and drive motor, and flushes blood elements from the seal of the pump assembly. The purge fluid, supplied by the user, is a sterile, biocompatible 40% dextrose solution USP (D40W). Fresh purge fluid is delivered to the pump at a flow rate of approximately 300 ml/day. Of this total daily flow, about 200 ml/day are released to the patient's circulatory system, while the remaining 100 ml/day are returned to a collection bag on the console.

Figure 4



– The console (shown in Figure 5) incorporates all of the power, control and diagnostic/alarm systems required to operate the pump and supply it with purge fluid. A portable, mobile unit weighing less than 25 pounds, the console can be mounted on the foot of the patient's bed, attached to the optional stand, or carried by hand. In order to facilitate gradual withdrawal of HEMOPUMP System support, the console can be run at seven different speeds. Normally powered by a standard AC line voltage source, the console also has battery backup for portable or emergency operation.

Figure 5



METHOD OF PLACEMENT

In the clinical experience to date, the HEMOPUMP System has been placed in position in approximately 20 minutes or less, without major open-chest surgery. First, the femoral artery in the patient's groin is exposed, and a segment of sufficient length to permit anastomosis of a 12 mm graft is isolated. After a woven, low-porosity graft has been anastomosed to the artery, the pump assembly is inserted through the graft, and is then advanced to the heart. The pump housing is positioned in the descending aortic arch, while the inflow cannula traverses the arch and passes retrograde through the aortic valve into the left ventricle (Figures 6 and 7). For transthoracic placement, a separate pump assembly, with a straight 9.5 cm cannula, is used.

Figure 6

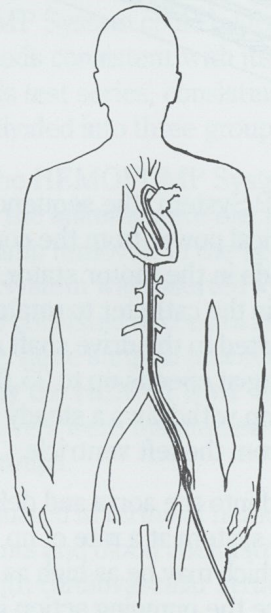
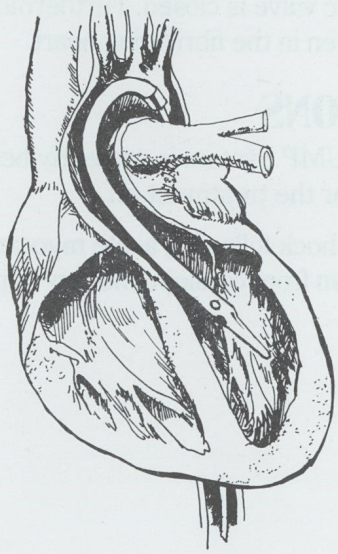


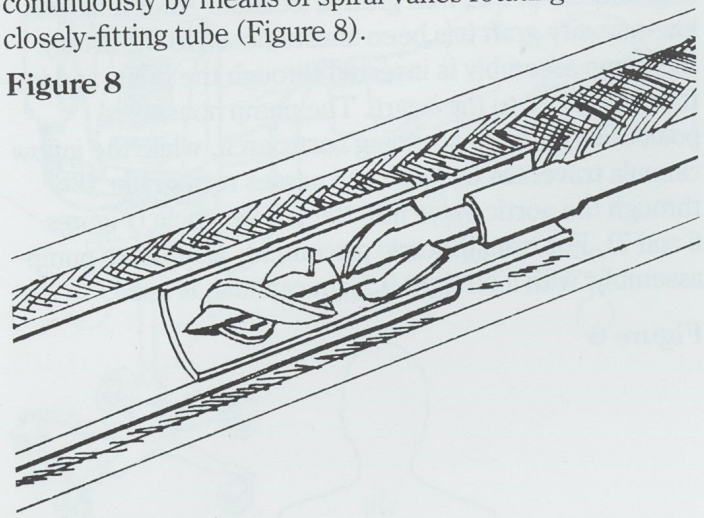
Figure 7



PRINCIPLES OF OPERATION

Unlike some other ventricular assist devices, which mimic the pulsatile action of the heart, the HEMOPUMP System utilizes a principle similar to that of the helically inclined plane, or Archimedes screw. Used for hundreds of years, the Archimedes screw traps and raises liquid continuously by means of spiral vanes rotating inside a closely-fitting tube (Figure 8).

Figure 8



In the HEMOPUMP System, the sequence of operation is as follows: Electrical power from the console pulses electromagnetic fields in the motor stator, causing the permanent magnet in the catheter to rotate. This spinning motion is then imparted to the drive shaft and the pump blades. Turning at speeds up to 25,000 revolutions per minute, the pump withdraws a steady stream of oxygenated blood from the left ventricle.

The blood is ejected into the aorta and delivered to the patient's circulatory system at a rate of up to 3 to 3½ liters per minute, which may be as high as 80% of resting cardiac output. Since the pumping action is continuous, blood flows through the pump even during diastole, when the aortic valve is closed. Furthermore, the pump can be used even in the fibrillating heart.

INDICATIONS

The HEMOPUMP System is presently being studied in clinical trials for the treatment of:

- cardiogenic shock following acute myocardial infarction
- failure to wean from cardiopulmonary bypass

PATIENT SELECTION CRITERIA

- pulmonary capillary wedge pressure greater than 18 mm Hg; and
- mean arterial pressure less than 90 mm Hg; and
- cardiac index less than two liters/min/M^2; and
- refractory to drug and volume therapy

CONTRAINDICATIONS

- significant blood dyscrasias
- bridge to cardiac transplantation
- recipient of a prosthetic aortic valve
- dissecting thoracic or abdominal aneurysm
- aortic wall disease
- severe peripheral vascular disease
- end-stage terminal illness
- severe aortic valve stenosis or insufficiency
- left ventricular thrombosis

POTENTIAL ADVERSE EFFECTS

Use of the HEMOPUMP System could produce adverse effects, including, but not limited to, the following:

- emboli, possibly leading to stroke or myocardial infarction
- vascular injury, including aortic dissection
- thrombus formation
- ischemia distal to insertion site
- ventricular ectopy
- infection and sepsis
- hemorrhaging
- valvular or endocardial injury
- hemolysis
- pump dependency
- death

IN VITRO TESTS

Hydraulic

Hydraulic testing was done in a blood analog medium, with the pump and cannula in the configuration subsequently used in the clinical trials.

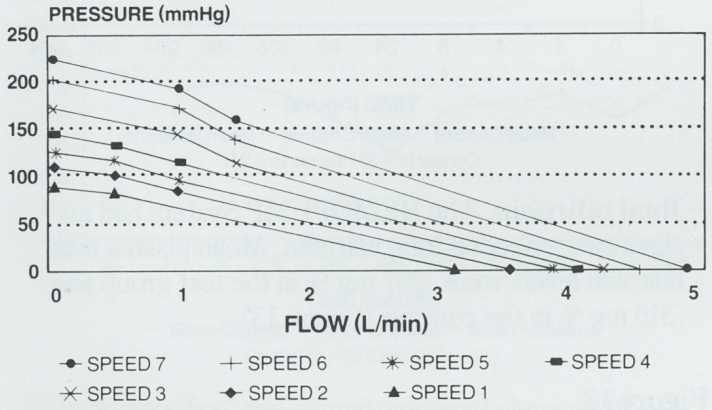
Flow through the HEMOPUMP System was found to vary as a function of pump speed and differential pressure across the pump. For a given pressure differential, the pump flow increased at higher pump speeds. When speed was held constant, the pump flow declined with increasing pressure differential.

Figure 9 shows the pump flow rate at each pump rate setting as a function of the patient's mean arterial blood pressure (with pump differential pressure assumed to be equivalent to mean arterial pressure). For example, when using the HEMOPUMP System at a pump rate setting of 7, with a mean arterial blood pressure of 80 mm Hg, the calculated flow of blood through the HEMOPUMP System is 3.1 liters per minute.

Figure 9

PUMP FLOW RATES AS A FUNCTION OF MEAN ARTERIAL PRESSURE* AT EACH PUMP RATE SETTING (*IN VITRO* TESTING)

(Values are for average pump performance; actual results in the clinical setting may vary.)



(The horizontal axis is pump flow rate in liters/minute; the verticle axis is pump differential pressure in millimeters of mercury.)

If a thermodilution catheter is used to measure cardiac output, the following equation may be used as a guide to determine the patient's heart function:

patient's heart function (liters/min) = cardiac output (liters/min) − pump flow rate (liters/min)

Endurance

Endurance tests were conducted on 10 HEMOPUMP Systems for 28 days in both pulsatile and static test loops. Motor current, purge pressure, seal flow and quantity of particulates were all monitored. The results show that:

- The HEMOPUMP System has demonstrated an endurance capability of at least 28 days.
- Particles in the 10-25 micron range were counted in the static test loops. Particulates contributed to the circulatory system by the HEMOPUMP System were in the range of $1.5\text{-}4.0 \times 10^3$/day. This is well below the limit of 50×10^3 set forth in the U.S. Pharmacopoeia XXI for a liter of large volume parenteral solution.

IN VIVO STUDIES

Approximately 65 *in vivo* animal tests, both acute and chronic, were conducted during the development program.

Characterization Studies

The objective of these tests was to determine whether the HEMOPUMP System could be tolerated by the host system for periods consistent with its intended clinical application. This test series, consisting of 24 experiments in calves, was divided into three groups.

In one group, the HEMOPUMP System was inserted for two weeks; the animals were electively sacrificed 28 days after pump removal. In the second group, the HEMOPUMP System was inserted for 1 to 14 days. The third group consisted of control animals which were subjected to the same surgical procedure, but were not supported by the HEMOPUMP System. Anticoagulant levels were maintained at 1½ to 2 times normal for all groups.

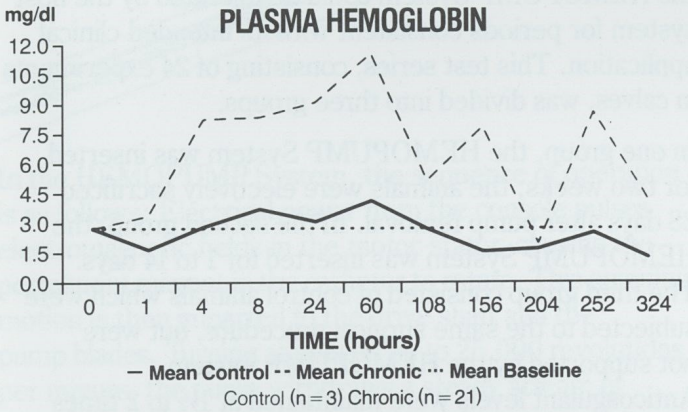
Safety was evaluated in terms of hemolysis, effect on blood elements and blood chemistry, anatomical compatibility with cardiovascular structures, and thromboresistance.

Hematologic Analysis:

The HEMOPUMP System did not cause any clinically significant impact on blood cellular or protein elements. Key tests are summarized below:

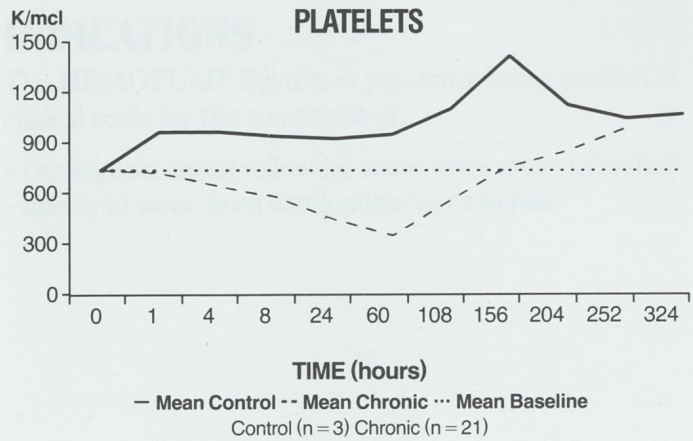
– **Plasma free hemoglobin.** Chronic levels of plasma free hemoglobin associated with HEMOPUMP System operation were only minimally elevated above baseline and were well below levels generally believed to be nephrotoxic. In the 21 chronic animals, the mean plasma free hemoglobin was 6.98 mg % (Figure 10). Only two animals exhibited chronically elevated plasma free hemoglobin levels (49 and 54 mg %) above the group mean. In neither case was the elevation attributable to the HEMOPUMP System.

Figure 10



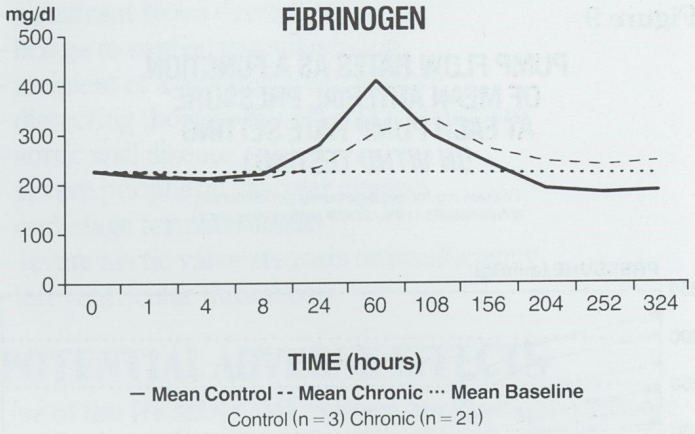
– **Platelets.** As a group, the 21 chronic animals tested exhibited a baseline of 799,000/mm^3 prior to HEMOPUMP System operation. This value remained stable for 24 hours after pump insertion. From then to the third day, the count declined to 315,000/mm^3, but it returned to normal on the fourth day (Figure 11).

Figure 11



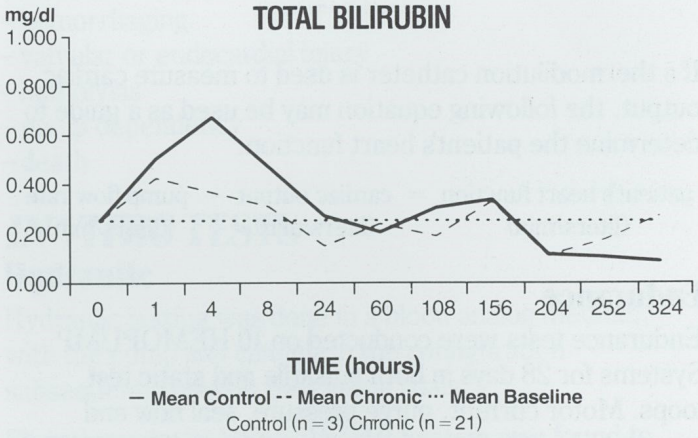
– **Fibrinogen.** Fibrinogen, which is essential to the normal clotting process, may be compromised by devices that pump or oxygenate blood. Mean values were 254 mg % in the chronic animals and 243 mg % in the controls (Figure 12). Therefore, no clinically significant decay in fibrinogen was noted.

Figure 12



– **Total bilirubin.** The HEMOPUMP System had no significant effect on total bilirubin. Mean plasma total bilirubin levels were .267 mg % in the test group and .316 mg % in the controls (Figure 13).

Figure 13



– **Renal function.** Compromised renal function is reflected by elevations of creatinine and blood urea nitrogen (BUN). The mean creatinine level averaged .93 mg % and was unremarkable (Figure 14). The mean BUN was 13.5 mg % in the experimental group of animals, and 11.22 mg % in the controls (Figure 15).

Figure 14

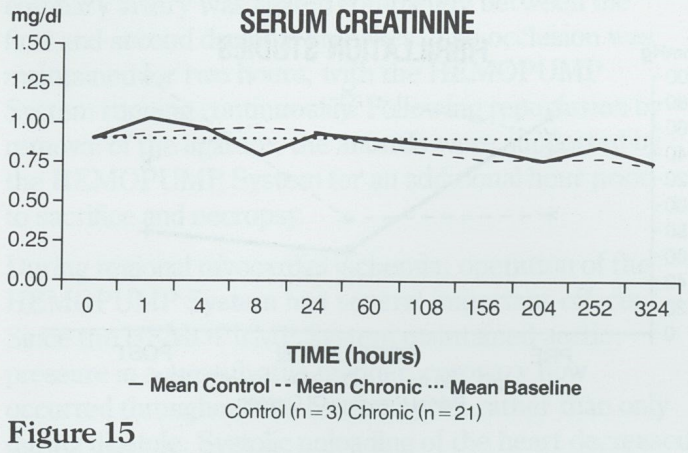
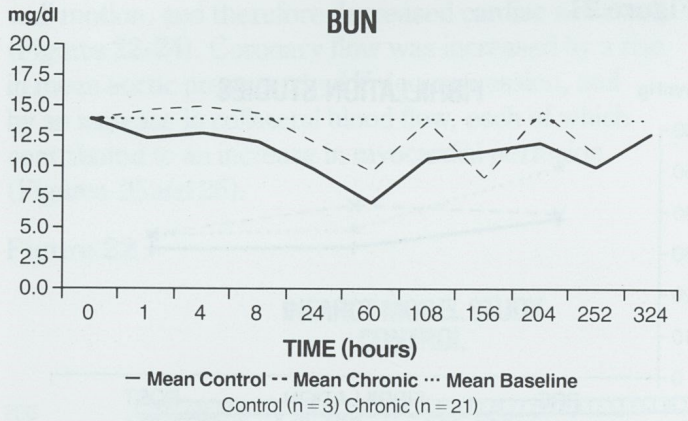


Figure 15



Prior to sacrifice, one animal exhibited elevated BUN of 39 mg % and a fall in hemoglobin from 10.2 grams to 7 grams. Necropsy of this animal revealed purulent encephalitis. Since serum creatinine and electrolytes were normal, the elevated BUN appears to have been due to hypovolemia from intra-abdominal hemorrhage.

Thromboemboli:

Renal cortical infarcts commonly occur in bovine kidneys following surgery or stress, particularly in the presence of blood pumping devices. In these studies, the pump assembly was inserted in the abdominal aorta above the renal arteries. Although some renal cortical infarcts were observed in most of the experiments, there was no correlation between these infarcts and thrombus deposition on the pump.

In more recent studies, involving six additional calves, the HEMOPUMP System was inserted in the carotid artery, and the animals supported for three to seven days. No renal infarcts were observed in these animals.

It is important to note that there were no thromboemboli in the brain, central nervous system or myocardium of any of the animals.

Pathology:

- Animals with proper HEMOPUMP System placement exhibited minimal abnormalities in intracardiac, valvular and vascular structures.
- The use of mobile calves with healthy hearts resulted in pump migrations and, therefore, some valve abrasion and hematomas.

Acute Fibrillation

This series of experiments was designed to demonstrate the ability of the HEMOPUMP System to perfuse the myocardium, and thus preserve myocardial contractility and hemodynamic performance, in the presence of ventricular fibrillation.

The HEMOPUMP System was inserted through the carotid artery of three adult sheep ranging in weight from 54 to 68 kg. The sheep were then subjected to 30 minutes of fibrillation. Operation of the pump, which does not require heart function, was commenced after onset of fibrillation.

Arterial and ventricular pressures, as well as regional wall motion, were evaluated both prior to and during fibrillation, with the HEMOPUMP System both on and off to assess its effect (Figures 16 and 17).

Figure 16

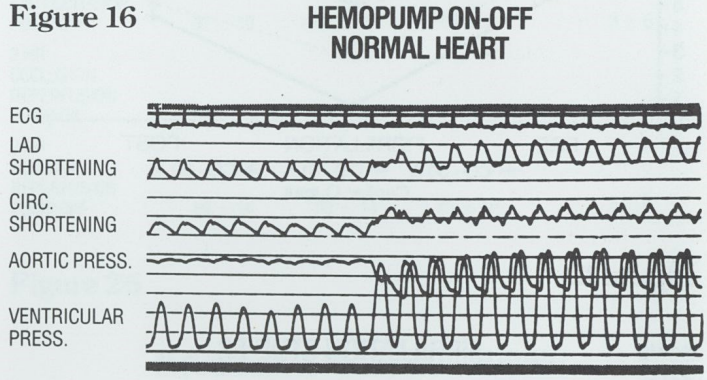
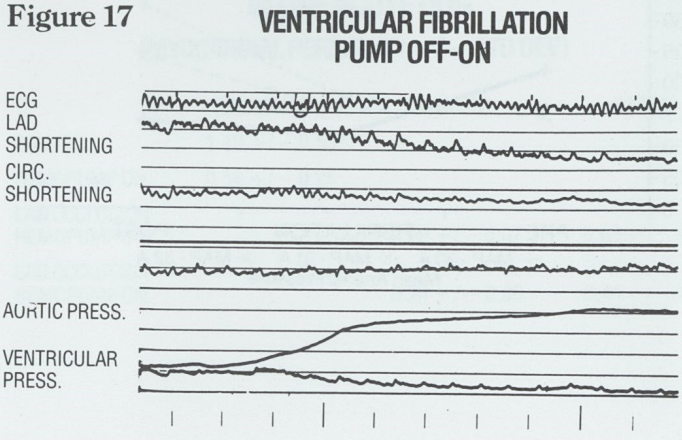


Figure 17



Without assistance to the circulation, ventricular fibrillation for 30 minutes would be expected to produce a profound, irreversible loss of myocardial contractility; an absence of cardiac output; an equalization of pressure in all chambers of the heart and throughout the vascular system; and decay of systemic blood gases to levels incompatible with life. In addition, defibrillation would be extremely unlikely.

However, because of the circulatory support provided by the HEMOPUMP System during the period of fibrillation, all of the experimental animals showed hemodynamic and blood gas evidence of active systemic perfusion and pulmonary circulation with oxygenation. Furthermore, all three animals were successfully defibrillated, following which significant LV function, cardiac outputs similar to baseline and blood pressure ranging from 80 to 160 mm Hg were observed (Figures 18-21).

Figure 18

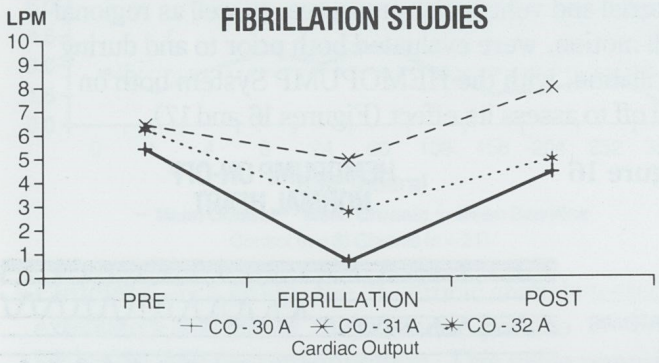


Figure 19

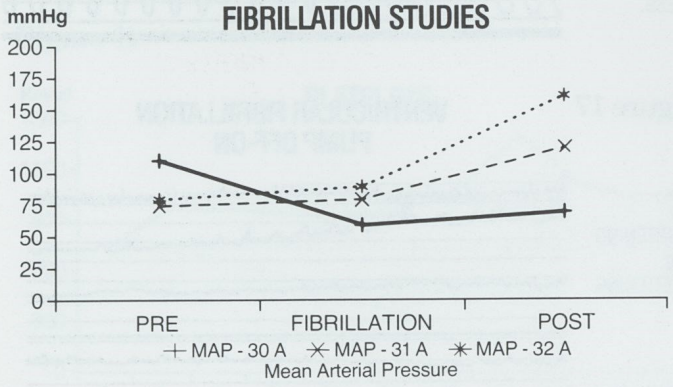


Figure 20

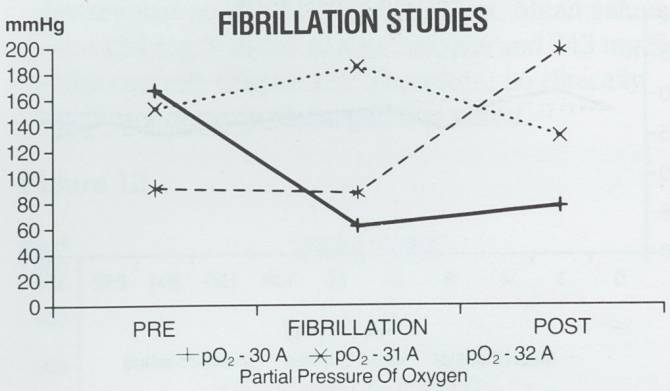
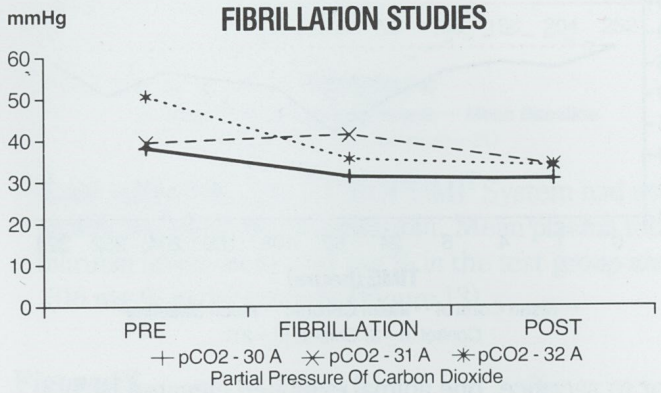


Figure 21



Technical difficulties with cannula placement in Animal 30A resulted in the inability to measure cardiac output accurately. However, the presence of increased aortic pressure, satisfactory arterial blood gases, and a successful defibrillation confirms that some degree of systemic flow occurred despite this impedance.

The results of these studies demonstrated that, despite the absence of heart function during the period of fibrillation, the HEMOPUMP System appeared to be hemodynamically effective in perfusing the myocardial tissue and maintaining peripheral circulation.

Acute Myocardial Perfusion

During coronary ligation, reduced blood flow will result in a loss of myocardial contractility, and, in time, irreversible necrosis, within the area at risk. Pilot studies in canines were designed to study the effect of the HEMOPUMP System on myocardial perfusion and preservation during acute coronary ligation.

In this series of experiments, the left anterior descending coronary artery was ligated completely between the first and second diagonal branches. The occlusion was maintained for two hours, with the HEMOPUMP System running continuously. Following reperfusion by removal of the ligature, the animals were supported by the HEMOPUMP System for an additional hour prior to sacrifice and necropsy.

During regional myocardial ischemia, operation of the HEMOPUMP System had several important effects. Since the HEMOPUMP System maintained aortic pressure in a nonpulsatile manner, coronary flow occurred throughout the cardiac cycle, rather than only during diastole. Systolic unloading of the heart decreased wall motion, and therefore decreased cardiac workload (Figures 22-24). Coronary flow was increased by a rise in mean aortic pressure, by LV decompression, and by an increase in collateral blood flow, each of which contributed to an increase in myocardial perfusion (Figures 25 and 26).

Figure 22

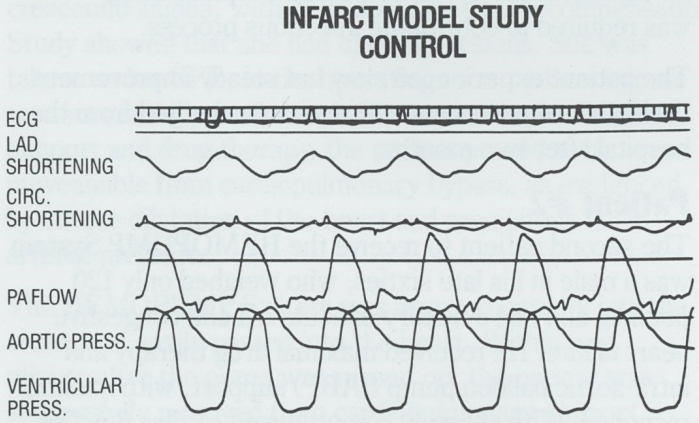


Figure 23

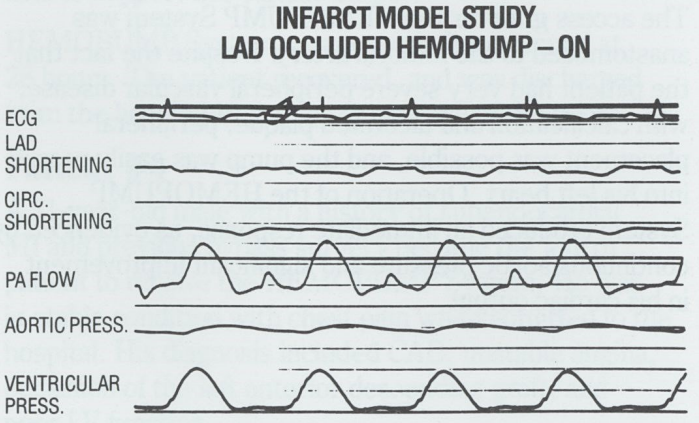


Figure 24

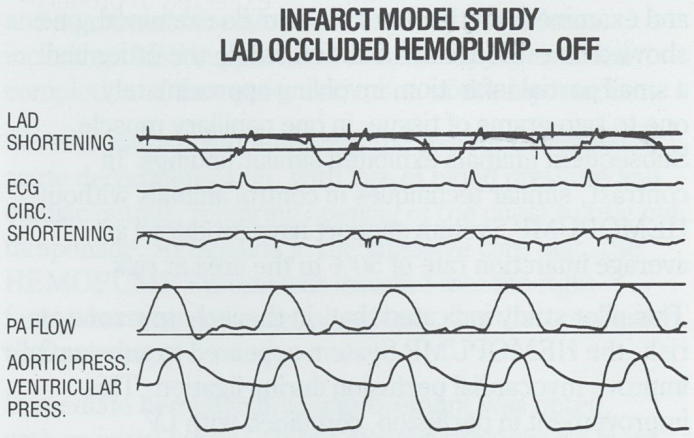


Figure 25

HEMODYNAMIC CHANGES DURING A 2 HOUR LAD OCCLUSION IN 3 ACUTE DOGS

CONDITION	LV SYSTOLIC PRESSURE (mmHg)	AORTIC SYSTOLIC (mmHg)	MEAN AORTIC PRESSURE (mmHg)	LV END DIASTOLIC PRESSURE (mmHg)
PRE OCCLUSION CONTROL	101 ± 9	107 ± 13	85 ± 13	3 ± 4
PRE OCCLUSION PUMP ON	97 ± 45	114 ± 17	99 ± 11	4 ± 5
LAD OCCLUSION PUMP ON	57 ± 40	96 ± 8	89 ± 13	1.5 ± 4
LAD OCCLUSION PUMP OFF	92 ± 10	87 ± 6	68 ± 5	3 ± 6
2 HR OCCLUSION REPERFUSION PUMP ON	59 ± 29	85 ± 8	74 ± 12	0 ± 6
2 HR OCCLUSION REPERFUSION PUMP OFF	89 ± 14	83 ± 14	63 ± 10	4 ± 4

Figure 26

MYOCARDIAL PERFUSION DURING EACH EXPERIMENTAL CONDITION IN ONE ACUTE DOG

(MYOCARDIAL PERFUSION +/– STD DEV)

	(ML/MIN/GM)	LAD BED	CX BED
CONTROL	1.10 +/– 0.55		
HEMOPUMP ON	0.59 +/– 0.28		
LAD OCCLUSION HEMOPUMP OFF		0.09 +/– 0.07	0.63 +/– 0.3
LAD OCCLUSION HEMOPUMP ON		0.24 +/– 0.08	0.44 +/– 0.2

After sacrifice, the hearts were removed from the animals, and the LV sectioned into serial slices, stained and examined. Of the first two animals examined, one showed no evidence of infarction, while the other had a small partial infarction, involving approximately one to two grams of tissue, in one papillary muscle. Subsequent animals exhibited similar findings. In contrast, similar techniques in control animals without HEMOPUMP System support have produced an average infarction rate of 50% to the area at risk.

This pilot study indicated that, in the ischemic zone at risk, the HEMOPUMP System appeared to substantially improve myocardial perfusion during ligation. This improvement in perfusion, combined with LV decompression, resulted in a return to normal contractility after the ischemic episode. Further studies have been initiated to substantiate these early findings.

CLINICAL STUDIES

Human trials with the HEMOPUMP System were begun in March of 1988. The first five patients to receive the HEMOPUMP System are described below.

Patient #1

The first recipient of the HEMOPUMP System was a 62-year-old male who had received cardiac transplantation for severe cardiomyopathy secondary to coronary artery disease (CAD). He subsequently developed pneumonia, which necessitated lowering his immunosuppression. This precipitated a severe, acute rejection of his transplanted heart, as shown by biopsy. The patient became acidotic, had a cardiac index of 1.9, and was aneuric. With profound cardiogenic shock that was unresponsive to very large doses of inotropic and vasoactive drugs, he appeared to be near death.

Since he was not a suitable candidate for an LV assist device or retransplant, this patient was selected as the first candidate for placement of the HEMOPUMP System. The rationale was that the HEMOPUMP System could provide cardiac and circulatory support while the rejection was reversed with a combination of cyclosporin A and OKT3.

Insertion of the HEMOPUMP System through the femoral artery, assisted by fluoroscopic visualization, was uneventful, and required only 18 minutes. Following placement, there was an immediate increase in the patient's cardiac output from about 3½ liters per minute on maximum inotropic support to up to 4½ liters per minute without any pharmacologic support.

For the first six hours after pump placement, the patient's own heart had little effective contractility. He was completely dependent on the HEMOPUMP System, and had a markedly abnormal ECG and a paced rhythm. By the following morning, however, he had spontaneously converted to a normal sinus rhythm, and cardiac function had begun to return.

The HEMOPUMP System was used to sustain the patient's circulation for 48 hours. During this time, the patient showed significant improvement in arterial blood gases, and in cardiac, liver and renal function.

Following removal of the HEMOPUMP System, the patient was able to support his own cardiac output, with minimal isoproterenol hydrochloride support. At the third day after removal of the pump, the patient's cardiac output without drugs was up to 6½ liters per minute, and his ejection fraction had increased from approximately 19% to over 50%.

One week after the initial biopsy, which had shown severe rejection, a repeat biopsy confirmed marked improvement in the histology of the cardiac muscle and reversal of his rejection. However, continued hospitalization was required to control the infectious process.

The patient experienced slow but steady improvement during his convalescence, and was discharged from the hospital after two months.

Patient #2

The second patient to receive the HEMOPUMP System was a male in his late sixties, who weighed only 120 pounds, and had a history of acute MI and congestive heart failure. He received maximal drug therapy and intra-aortic balloon pump (IABP) support, with minimal response. With severely compromised cardiac function (cardiac index <2 liters per minute), pulmonary edema and hypotension, the patient was facing imminent death.

The access graft for the HEMOPUMP System was anastomosed to the femoral artery. Despite the fact that the patient had very severe peripheral vascular disease, with calcification and ulcerated plaque, peripheral placement was possible, and the pump was easily passed into his left heart. Operation of the HEMOPUMP System produced an immediate response, as evidenced by continuous aortic pressure and significant improvement in his cardiac output.

Within 48 hours after insertion of the HEMOPUMP System, chest X-ray confirmed that the patient's heart size had returned to normal, and his lungs were markedly clear of edema; in addition, there was a significant improvement in his blood gases, and an increase in his cardiac output to 5½ liters per minute.

Cardiac function was supported by the HEMOPUMP System for five days. During this period, the patient was responsive at times, but could not be weaned from circulatory support.

At the family's request, the device was removed on the fifth day. The patient died within 30 minutes after removal. Cause of death was irreversible heart disease and complications not related to the pump. Necropsy evaluation showed no injury to the aortic wall, aortic valve or intracardiac structures. An old ventricular aneurysm and evidence of a new posterior wall infarction were noted.

Patient #3

The third recipient of the HEMOPUMP System was a 70-year-old woman who had a history of CAD and crescendo angina, with developing cardiac decompensation. Study showed that she had operable lesions. She was taken, under CPR, to the operating room, where bypass was successfully performed. However, despite IABP support and drug therapy, the patient proved to be unweanable from cardiopulmonary bypass, as evidenced by severe dilatation of the heart and precipitous fall in arterial pressure.

The HEMOPUMP System was inserted directly into the aorta, and easily passed into the heart. Within one minute after the pump was turned on, the patient was successfully removed from cardiopulmonary support. Following brief administration of inotropic drug therapy, LV function was rapidly regained, and the patient was able to support her cardiac output.

HEMOPUMP System support was discontinued at 28 hours. The patient recovered, and was discharged from the hospital 10 days after removal of the pump.

Patient #4

A 71-year-old male with a history of subendocardial MI and previous bypass surgery became the fourth patient to receive the HEMOPUMP System. He was in stable condition with chest pain when admitted to the hospital. His diagnosis included CAD, unstable angina, occlusion of the left anterior descending graft, and poor LV function.

The patient underwent coronary artery bypass. During opening of the sternum, he experienced cardiac arrest and significant blood loss. Emergency procedures, including IABP support and drug therapy, permitted completion of the revascularization of the myocardium.

Several hours postoperatively, the patient developed acute decompensation, with loss of blood pressure and cardiac output, requiring opening of the chest to rule out tamponade. At bedside in the intensive care unit, the HEMOPUMP System was inserted into the right femoral artery, and exact placement was then confirmed by fluoroscopy.

Immediate hemodynamic improvement was noted, with an initial cardiac output of approximately 4½ liters per minute. During HEMOPUMP System assistance, the patient had good urine output, acceptable arterial blood gases, and evidence of good cerebral perfusion. However, very high CVPs and poor LV filling provided evidence that severe right heart failure had developed, and it became impossible to maintain adequate cardiac output.

The patient's family elected not to intervene with any further assistance, and the HEMOPUMP System was removed without complications. The patient died 10 minutes after pump removal. The cause of death, massive MI with low-output syndrome, was judged to be unrelated to the HEMOPUMP System. Necropsy evaluation showed no injury to the aorta, aortic leaflets, myocardial wall or femoral artery.

Patient #5

A 48-year-old male became the fifth person to receive the HEMOPUMP System. The patient's history included an acute inferior wall MI and balloon angioplasty to the right coronary artery, both in 1985. When admitted to the hospital in 1988, he had unstable angina and an ejection fraction of 40%.

A coronary artery bypass was performed. Perioperatively, the patient suffered an anterior MI, as evidenced by elevated serum creatine phosphokinase, and postoperatively, he developed a clot in the right internal mammary artery.

The patient was returned to surgery for another vein graft, after which an IABP was inserted because of decreased LV function. In the coronary intensive care unit, he continued to be unstable, and developed profound hypotension and cardiogenic shock secondary to LV dysfunction.

As a result, he was again returned to surgery for placement of the HEMOPUMP System, through a cutdown of the right femoral artery. Immediately after placement, cardiac output was 4½ liters per minute, without IABP assistance. Drugs were discontinued at the operating table. When returned to intensive care, the patient was in stable condition.

Three and one-half hours postoperatively, the device was removed. The patient remained stable, and his cardiac performance was maintained without drugs.

The patient was discharged from the hospital to recuperate at home.

CONCLUSIONS

Animal studies and clinical experience to date suggest that the HEMOPUMP System may provide greater hemodynamic support than the IABP. Furthermore, this is accomplished without either the major surgery associated with the LV assist device or a clinically significant level of hemolysis.

Patients who cannot be weaned from cardiopulmonary bypass or are in cardiogenic shock are currently managed with pharmacological agents and occasional use of the IABP. In such patients, the HEMOPUMP System can provide decompression of the LV, and cardiac flow of up to 3 to 3½ liters per minute, which may be as high as 80% of resting cardiac output.

Caution– INVESTIGATIONAL DEVICE, LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE.

Johnson & Johnson

INTERVENTIONAL SYSTEMS

a Johnson & Johnson company

35 Technology Drive, P.O. Box 4917
Warren, New Jersey 07060 U.S.A.
1-201-218-7807

Printed in U.S.A.