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A mechanical biventricular assist device

Andrew Armour
Lehigh University

A MECHANICAL
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(date)

Professor Eric P. Salathe

Professor Robert P. Wei
Chairman of the Department

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Abstract

The study, design, and fabrication of a new cardiac assist device has been conducted. The cardiac assist device, following further evaluation and clinical trials, will be suitable for use at several levels of cardiac dysfunction.

1. Patients completing cardiac surgery with weakened contractility, requiring short term cardiac assistance.
2. Patients with such severe cardiac dysfunction that support is required while awaiting a transplant.
3. Patients with slightly damaged or weak hearts that require long term assistance in order to provide the appropriate circulation volumes.
4. Patients at a high risk of heart attacks, where the unit would remain dormant until activated by a signal when an impending heart attack is sensed.

The new cardiac assist device aids the heart by compressing the exterior of the heart, thereby eliminating contact with the flow of blood. The assist, termed a mechanical biventricular assist device (MBAD), was formed by dipping a mold into a dispersion of bio-compatible polyurethane material. Bladders formed in the process are used to perform the compression of the heart by pneumatically pressing the ventricle walls. The device was tested in the laboratory on pig hearts, and found to functional well.

The entire design and development process, which examines several actuation techniques, different configurations and materials for the MBAD, and details of the fabrication and testing procedures is discussed. Different methods for refined development and continued testing of the device are also outlined.

1.0 Introduction

Cardiovascular disease remains the single greatest cause of death in the United States, and it is estimated that two-thirds of these deaths are caused by failure of the left ventricle to sufficiently pump blood through the body [1]. There are currently drugs that may help or cure this problem, though there are many conditions in which the drugs are not effective (ie. allegic reactions, severe conditions etc.). This has prompted the continuing development of mechanical devices that may replace or assist the human heart.

The concept of replacing or assisting the pumping action of blood by the human heart is by no means new. As early as 1812, this concept was formulated as a means to prolong the human lifespan [2]. Over the past several decades, many concepts have been advanced to either replace or assist the heart, though development of a safe, reliable, and physiologically stable device still remains to be accomplished.

There are three currently available mechanical circulatory assist devices, each with several shortcomings- a totally artificial heart (TAH), a left ventricular assist device (LVAD), and an intra-aortic balloon pump (IABP). The three devices, and their shortcomings will be described briefly, after which an alternative method will be described and its development discussed in the remainder of this thesis.

1.1 Current Mechanical Circulatory Assist Devices

A totally artificial heart (TAH), originally conceived as a means to circumvent the need for transplants, presently appears destined only to keeping a patient alive until a donor heart can be found. This is due to the many possible complications that may occur [3]:

a. Emboli (release of a thrombus), which may result in stroke, loss of kidneys, liver, bowel or lung, or partial impairment of organ or body function.
b. Malfunction or mechanical failure of the artificial heart device.
c. Infection of the blood, the drive lines to the artificial heart device, or infection of the artificial heart device itself.
d. Hemorrhage resulting from the action of the artificial heart device upon vessels, surgery to expose the heart, or other causes.

e. Damage to the red blood cells that carry oxygen and carbon dioxide, the platelets that cause blood to clot, or white blood cells that act as scavengers against foreign substances and provide for immunization, which might cause a change in the blood immune system or anemia.

f. Internal hemorrhage due to deficiencies in the blood clotting mechanisms secondary to the artificial heart.

g. Pneumothorax. Air in the chest cavity, which may result in difficulty breathing, requiring a separate tube to be placed in the chest.

Implanted left ventricular devices (LVAD) have been limited thus far to assisting the pumping of blood while the heart recovers from surgery, or while a patient awaits a donor heart for transplant. The LVAD is a hollow chamber that is placed within the left ventricle, in which a bladder fills with blood. Pneumatic pressure between the chamber wall and the bladder is used to pump the blood. Efforts are underway to develop totally implantable LVADs, though many of the complications noted for the TAH also exist for the LVAD, which present difficulties to this type of development.

Intra-aortic balloon pumps are the most widely used form of mechanical heart assist devices [4]. They consist of a thromboresistant envelope mounted on a catheter that is placed in the descending aorta in order to reduce work by the failing left ventricle. The envelope is inflated during the filling of the heart. As the heart begins to pump, the envelope is quickly deflated, which provides a void equivalent to the approximate volume of the balloon for which the left ventricle can fill at a lower pressure than normal. When properly timed, the IABP significantly reduces the load that the left ventricle must pump against, thereby assisting the heart. Again, several possible risks are associated with the use of the IABP, including thromboemboli formulation, ischemic damage to tissues or organs downstream from the balloon, gas emboli, tears or perforations in the aortic wall, and infection.

1.2 Direct Mechanical Ventricular Assistance

More than twenty years ago, Anstadt, Schiff, and Baue [5] developed a method of

externally 'massaging' the human heart in such a manner as to compress the ventricles pneumatically, thereby externally pumping the heart. The cup shaped device was a significant improvement over previous attempts to develop such a device [6] - [12]. Experimental and clinical evaluations of the Anstadt cup were made by Skinner [13], who showed its effectiveness in cardiac resuscitation following induced ventricular fibrillation, and in providing total circulatory support for a limited time during acute myocardial infarction.

This concept of 'massaging' the heart externally eliminates many of the recurring problems that exist when the assisting device comes in contact with the blood, or involves incisions made to the heart. The assist does not require the removal of the heart or any of its parts, and may be applied quickly, and without significant difficulty to the damaged heart either as a bridge to transplant, as a means of assisting the heart after an operation, or as a permanent assist to a diseased heart. When necessary in extreme cases, prosthetic bovine valves can be used to replace degenerated natural valves, and damaged septums can be repaired.

1.3 A New Direct Mechanical Ventricular Assist Device

Research and development is currently being conducted in order to develop a new cardiac assist device that will externally 'massage' the heart in a similar manner to the Anstadt cup. The development of new bio-materials, a better understanding of cardiac physiology, and a new role for circulatory assist devices as a bridge to cardiac transplantation are compelling reasons for this effort.

The development, manufacturing, and testing of a mechanical biventricular assist device (MBAD) will be discussed in the following chapters.

2.0 Background

In order to clearly present the development of a mechanical biventricular assist device (MBAD), it is important that one understands the physiology of the human heart. This can be done by referring to the references [14] through [17]. For ease of referral to

the structure and the path of blood flow in the heart, four drawings (figures 2.1-2.4) are provided [15]. The pumping technique and effects will be the discussion of this chapter.

2.1 Pumping Technique

External 'massaging' of the heart in order to assist the pumping action requires a mechanical means to compress the walls of the heart directly opposite both the left and right ventricles (see figure 2.2 for orientation of the left and right ventricles). An overview of the different mechanical methods available to accomplish this action is the discussion of the following chapter, though before these methods could be developed, an understanding of an efficient pumping technique was necessary. The best way to decide on an efficient means of pumping the heart was to actually pump a heart. Due to the similarities in size and physiology of a pig heart with the human heart (as well as the accessibility of pig hearts from the local butcher), pig hearts were obtained, prepared and tested.

2.1.1 The Preparation of Pig Hearts For Pumping

Pig hearts were obtained from the butcher (Barringer Bros.) as soon as possible after slaughtering (between 1 to 3 hours). The hearts were stored in a refrigerator when not being prepared or tested. A pig heart obtained from the butcher is very different from anything seen in a physiology book. The heart is enclosed in the pericardial sack, which is attached directly above the two atrium. All arteries and veins attached to the heart are almost unrecognizeable due to being covered with fat . The preparation of a heart began with the removal of the pericardial sac, and the thorough washing of the interior and exterior of the heart by flushing with water for several minutes. All of the fat attached to the aorta, pulmonary artery, superior vena cava, and pulmonary veins could then be carefully removed with forceps and surgical scissors. This was essential for good connections to be made to these arteries and veins. Plastic fittings, formed from polyethylene tubing attached with plastic o-rings, could then be inserted into each of the tubes (aorta, pulmonary artery, superior vena cava, or pulmonary veins), and held tight by tying circumferentially with surgical thread and knotting. This was done for each of the

four tubes, and all other openings to the heart were closed by tying with surgical thread in a similar manner, but without use of the plastic fitting. The prepared heart was now ready to be pumped externally by means of the hands.

2.1.2 Pumping of the Pig Hearts

In order to apply the appropriate pressures to the heart, the heart was pumped into a test stand (shown in figure 2.5). Columns of water were used to replicate the 120mm Hg (64.3" H_2O) pressure of the left ventricle, and the 25mm Hg (13.4" H_2O) pressure of the right ventricle. The system is an open system in which water flows into the ventricles from a reservoir. Each ventricle connects to a separate reservoir, and pumps into the appropriate column of water, which overflows into another column to indicate cumulative flow. The fittings on the heart were attached to the appropriate columns of water, which enabled the heart to fill with water. By squeezing the heart with the fingers, the heart was compressed, consequently forcing water from the ventricles into the water columns.

Labelled in figure 2.2, and shown clearly in both figure 2.3 and figure 2.4, is the interventricular septum that separates the left and right ventricles. This layer of material disables efficient compression of the ventricles perpendicular to this wall. It was found, through the pumping of more than 10 pig hearts, that the most efficient pumping was accomplished by squeezing the myocardium directly opposite the center of each ventricle.

2.1.3 Other Considerations

It is essential that shearing forces on the surface of the heart are minimized during external massaging of the heart, to avoid possible damage to the heart's myocardium. The ideal action to take place would be a motion of the expanding assist device that would pointwise match the contracting surface of the heart at all stages of the contraction and expansion cycle. Due to the unlikeliness of this occurance, several contact surfaces were envisioned that would mediate the moving contact zones. The different surfaces developed- gelatin, hinged fluid spheres, villi, and composite layers- all convert a normal and shear force into the normal component only. The different surfaces are pictured in figure 2.6. An

alternative to these different contact surfaces is the use of a very low friction substance on the interior of the assist device that would eliminate any frictional damage to the surface of the heart by the shearing action.

The pumping of the left ventricle in a dead heart is considerably more difficult than for a living heart, due to a significant increase in the rigidity of the myocardium. The expansion of the left ventricle upon filling is therefore greatly reduced, preventing the correct volume to fill the ventricle and thus be pumped from the ventricle. A larger filling pressure may increase the exchanged volume.

3.0 An Overview of Possible Actuation Techniques

There are many methods of massaging the exterior of the heart in order to produce a pumping action. Before pursuing one technique, several were studied. Considered were three pneumatic actuation techniques, and six mechanical actuation techniques.

3.1 Pneumatic Actuation

Pneumatic actuation implies that a pressurized gas is used to provide the force needed to compress the heart. The main advantage of pneumatic actuation techniques are that they are rather simple compared to mechanical actuation techniques. The main disadvantage is that the pumping mechanisms to provide the pressure are currently too large to be implanted or even to be considered portable. The different possiblities for pneumatic actuation include bladders, pistons, and contracting tubes.

A pneumatically actuated bladder (shown schematically in figure 3.1) is a simple and effective means of contracting the heart. Bladders that are adjacent to both ventricles are inflated to push against the outer ventricle walls in order to pump the blood. The advantages of a bladder are ease of fabrication and reliability, for there are minimal moving parts. The major disadvantage is that it requires a large volume of pressurized gas for each actuation stroke. Each stroke can take up to 150 ml (5.07 ozfl) of gas, and at an average of 75 beats per minute, this is over 11 liters (3 gal.)of gas per minute. The shuttling of this much gas per minute makes the possibilities for a portable pumping unit currently

impossible.

A pneumatically actuated piston arrangement (shown schematically in figure 3.2) can be substituted for the bladders. The major advantage with this is that lower volumes of gas are required for smaller piston diameters, although the required pressures increase as a function of the decreasing area. The problem with a piston-cylinder arrangement is that the motion of the piston would have to be linked to the contraction of the heart through a mechanical arrangement that could be somewhat awkward.

Flexible piston-like tubes (shown schematically in figure 3.3) that contract under a vacuum may be used to contract the heart in a similar manner to actual muscular heart contraction. Since the tubes may be small in diameter, they will have a small volume, so high vacuum will be required in order produce a significant contraction. With many separately controlled tubes surrounding the heart, a good simulation of the muscle contraction sequence may be obtained around the heart.

3.2 Mechanical Actuation

Mechanical actuation systems rely on electrical power to activate some sort of mechanical linkage that can convert an input motion into the desired massaging motion on the heart. The different mechanical actuation methods studied were cams, linked pivot plates, iris plates, windup bands, rigid diaphragms, and shape memory wires. The advantages of these methods are that they can all be electronically controlled through the use of microprocessors. The main disadvantage is that the mechanisms for motion conversion are quite complex and inefficient.

Cams (shown schematically in figure 3.4) may be used to compress the heart by sliding in a circular motion until the longest side is adjacent the ventricles. They may be contoured so that their motion accurately matches that of the actual heart motion. The cams would be moved via a motor and a series of gears. The main drawback is that shear forces will be applied to the surface of the heart unless a low friction contact surface is applied.

A series of plates (shown schematically in figure 3.5) may be linked together so that they move equivalently from a flat position parallel to the outer surface of the heart, to

a position perpendicular to the heart. Acting in a similar method to the cams, this could be contoured to match the hearts pumping motion. The main drawback for cams also exists here.

An iris plate (shown schematically in figure 3.6) is a mechanical arrangement that resembles the apperature of a camara. Sliding concentric rings form a band around the heart that can slide to form a larger or smaller opening, relaxing or contracting around the heart. A series of these mechanisms vertically along the heart will provide contraction over the positioned area. The main drawback with this technique is that the contraction is circumferential, which is not as effective as pressure directly opposite the two ventricles.

Windup bands (shown schematically in figure 3.7) consist of a series of flexible bands that are wound around the heart. Each band may be quickly wound up and tightened around the heart during contraction, and relaxed during diastole. The main concern with this method is avoiding pinching and excessive friction on the heart surface. This could be minimized by increasing the number of segments and windup locations on each band. The same drawback with the iris plates also exists with this technique.

Rigid diaphragms (shown schematically in figure 3.8) consist of a thin shell that may flip into a concave or convex shape upon being impinged by a point force. The diaphragm would be the end effector of a controlled point force actuation such as a cam or piston, and would effectively convert a point force into a surface pressure.

The final conceptual mechanical actuation system utilizes the material forces of shape memory alloys (shown schematically in figure 3.9). These alloys, under a change in temperature, change dramatically in size almost instantly. Electrical current can generate the required heating of a wire, which shrinks to compress a fluid filled sack. This sack, acting in a similar way to a diaphragm, could apply a surface pressure to the heart. Limitations to this concept include heating and cooling times of the shape memory wire, as well as excessive heat to the heart.

3.3 Conclusion

A pneumatically actuated bladder was decided to be the most effective means to

accomplish external pumping of the human heart. This decision was based on reliability, adjustability, control, existing technology, and several physiological aspects.

With only one moving part, the reliability of a bladder actuated MBAD is much higher than any other of the considered techniques. This is a very important consideration when working with a medical application. Adjustability is very easy with bladder actuation, for different bladder sizes and shapes can be produced and positioned in various orientations against the heart surface. Different sizes of the device can also be fabricated easily once the fabricating techniques are understood. Control of actuation forces and times are easily adjusted by adjusting gas pressure and flow, for which the technology already has been developed. Intra-aortic balloon pumps and left ventricular assist devices operate in a very similar manner to a bladder, and the technology exists for their fabrication, as well as pumping and control. A bladder is also capable of compressing the ventricles in a manner for which little shear force is applied to the heart surface. This is possible by mapping the contraction of a heart, and having the bladder closely follow this pattern.

4.0 The Outer Shell

Once it was decided to use a bladder to contract the heart, it was necessary to determine the formulation for an outer shell that would contain the bladder. There are three possibilities for the hardness properties of the enclosure. The shell can be rigid and inextensible, flexible and extensible, or flexible and inextensible. Also, the shell can be formed in different sizes, or made adjustable to allow for different heart shapes and sizes. The idea of a soft and extensible outer shell is quickly dismissed, for it would not allow reactive forces of the bladder to be directed against the heart, but rather would expand outwardly. Both rigid and flexible inextensible shells that are either adjustable or non-adjustable were studied.

4.1 A Rigid Enclosure

A rigid enclosure for the heart has the greatest disadvantage in that it has a potential for internal damage to the body by impacting objects in the thoracic cavity if its exterior is

not padded. A rigid shell is advantageous in that once attached to the heart, its rotational and sideways movement is limited, and all bladder movement is controlled to move directly inward to compress the heart.

For testing the feasibility of a hard shell enclosure, a clamshell design was developed (see schematic in figure 4.1). The clamshell consists of a half shell that fits over each ventricle. The two half shells are connected together along the edges to form a complete enclosure. With a bladder in each half shell, each ventricle can be compressed with the inflation of each bladder. The connection along the edge of each shell would be adjustable to allow for different heart sizes. A prototype was developed and is discussed in detail in chapter 7.3.

4.2 A Flexible Enclosure

An inextensible flexible enclosure has the advantage of having less potential for internal damage to the body, as well as possessing several easy adjustment capabilities, enabling it to fit most heart sizes. If formed or adjusted into the correct shape, an inextensible flexible enclosure will not allow any rotational or sideways movement of the heart, and allow all reactive forces from the bladder to be directed in against the ventricle walls.

Two methods of adjusting the inextensible flexible outer shell once it has been fabricated are with shrink fitting materials or commonly used wire mesh (shown schematically in figures 4.2 and 4.3 respectively). A shrink fitting material could be used in the shell construction, and would allow small adjustments in size by shrinking upon exposure to either heat or ultraviolet light. A wire mesh, commonly used in many surgical applications, could be formed around the outer shell and adjusted by tightening the mesh at its intersection points. The disadvantage of this means of adjustment is the possibility of creases formed in the shell under the wire mesh at adjustment points.

5.0 The Bladder

A bladder that would fill and expand with gas is required inside of the outer

enclosure in order to provide the compression forces to the heart. The bladder, as with the outer shell, has several possible characteristics. The bladder may be either extensible or inextensible, and may be either completely self contained or rely on the shell wall for containment of the gas upon filling.

5.1 An Extensible Bladder

An extensible elastic bladder has the advantage of expanding to compress the heart, thereby providing a very even pressure distribution without wrinkling. Its greatest disadvantage is that it will cause shear forces against the heart surface as it expands. Care must also be taken to ensure that after repeated cycling of the bladder, plastic deformation does not occur, thereby resulting in wrinkling.

5.2 An Inextensible Bladder

An inextensible bladder has the disadvantage of being wrinkled when evacuated. This will cause shear forces against the heart surface until all the wrinkles have undone, at which time, the bladder may follow the heart surface in a point to point fashion (each contact point of the expanding bladder will match a point on the surface of the heart throughout the expansion process) if fabricated accordingly. This is accomplished by mapping the heart surface during contraction, and fabricating a bladder that will follow this pattern.

5.3 A Self- Contained Bladder

A bladder that is completely self- contained possesses the problem of applying pressure in the correct places to the heart surface. As the bladder is inflated, it will tend to move to the point of least resistance. This will occur if the bladder is extensible or inextensible. For example; a rubber balloon may be placed on a flat table under a flat plate. If a weight is placed upon the plate, and the balloon is inflated, the balloon will tend to expand outwards until it protrudes from the edge of the plate (if the plate is small enough), and then expand in its third dimension. This reaction does not allow for an even control of

pressure against the heart surface. This may be eliminated by fixing the bladder to the inner wall of the outer shell, or using the interior of the outer shell as a containment for the gas, as will be discussed in 5.4.

5.4 A Shell- Contained Bladder

A bladder that relies on the interior of the outer shell to be enclosed has the advantage of positioning and control, for its movement is limited to an outward inflation. With the required pressure, an extensible bladder that is attached along its edges to the inner wall of the shell will always inflate in the same pattern. This is not true for an inextensible bladder, which will inflate differently every time during its unwrinkling period. The disadvantage of a bladder that is not self- contained is that it must be attached via a seam to the shell's inner wall. This seam is a potential leak hazard.

Because of the uneven control capabilities of a self-contained bladder, only the development of a bladder connected to the outer shell was pursued. Both extensible and inextensible bladders were tested as possible methods (see chapter 7.3 and chapter 11.2).

6.0 Development of a Replica Mold

A bladder actuated MBAD must accurately fit the heart that it will pump to ensure proper bladder orientation and minimize slippage of the device on the heart. A small amount of adjustment can be made with the outer shell (as discussed in chapter 4), though this assumes that an accurate fit has already been made. All experiments and testing of the MBAD involve the use of pig hearts (see chapter 2), so it is natural that the designed MBAD be fitted to a pig heart. Rather than work with pig hearts for the fabrication process, requiring the measuring and forming of the bladder and shell on the heart itself, a male mold of the pig heart was developed.

6.1 First Prototype Mold

In order to produce a replica of a pig heart, a female mold was made from an actual pig heart. This was then used to produce the male mold. The process is discussed in

the following paragraphs.

For a female mold to be made from the heart, the procedure for preparing hearts for testing (discussed in chapter 2.1.1) is followed, except that no connections are attached. The heart is then put in a freezer for 12 hours to freeze. When removed, the heart is ready to be prepared for molding.

A strong soap solution was made using dishwasher liquid and water (about 10 parts soap to 1 part water). This was to be used as a release agent on the heart surface. The soap solution was applied by hand in a thin layer to the heart, completely covering all exposed surfaces. The heart is then covered with a layer of silicone II® rubber (about 1/4" thick). Silicone is used because it conforms very well to objects, and possesses sufficient elasticity for the object to be easily removed. A layer of gauze is used to give a surface for the silicone to stick to as well as add strength to the mold. Two more layers of silicone and gauze were alternated upon the first layer in the same fashion, after which the mold was allowed to dry for 12 hours.

At this point, the difficulties encountered in the process should be mentioned. With the soap release agent on the heart surface, it was very difficult to make the initial layer of silicone adhere in any manner to the surface. By coating the gauze with silicone, a gauze silicone composite was able to be applied appropriately. The following layers presented no problems. When the silicone had fully cured, a 3" slit at the top of the silicone mold was made with a knife and scissors. This provided enough room to remove the heart, which was then discarded. The interior of the mold was then washed thoroughly with water, and a thin layer of the soap solution was allowed to coat the inner surface to provide a release agent for the molding process.

Plaster of Paris was the material used to fabricate the male replica. The plaster was mixed with water according to the directions (about 800 ml (27 ozfl.) volume total), and poured into the mold (from the top slit) in four steps, tapping the mold on a table in between each addition to relieve trapped air bubbles. When the mold was completely full of plaster, it was carefully positioned upright in between three boxes, and allowed to dry for 12 hours.

the following paragraphs.

For a female mold to be made from the heart, the procedure for preparing hearts for testing (discussed in chapter 2.1.1) is followed, except that no connections are attached. The heart is then put in a freezer for 12 hours to freeze. When removed, the heart is ready to be prepared for molding.

A strong soap solution was made using dishwasher liquid and water (about 10 parts soap to 1 part water). This was to be used as a release agent on the heart surface. The soap solution was applied by hand in a thin layer to the heart, completely covering all exposed surfaces. The heart is then covered with a layer of silicone II® rubber (about 1/4" thick). Silicone is used because it conforms very well to objects, and possesses sufficient elasticity for the object to be easily removed. A layer of gauze is used to give a surface for the silicone to stick to as well as add strength to the mold. Two more layers of silicone and gauze were alternated upon the first layer in the same fashion, after which the mold was allowed to dry for 12 hours.

At this point, the difficulties encountered in the process should be mentioned. With the soap release agent on the heart surface, it was very difficult to make the initial layer of silicone adhere in any manner to the surface. By coating the gauze with silicone, a gauze silicone composite was able to be applied appropriately. The following layers presented no problems. When the silicone had fully cured, a 3" slit at the top of the silicone mold was made with a knife and scissors. This provided enough room to remove the heart, which was then discarded. The interior of the mold was then washed thoroughly with water, and a thin layer of the soap solution was allowed to coat the inner surface to provide a release agent for the molding process.

Plaster of Paris was the material used to fabricate the male replica. The plaster was mixed with water according to the directions (about 800 ml (27 ozfl.) volume total), and poured into the mold (from the top slit) in four steps, tapping the mold on a table in between each addition to relieve trapped air bubbles. When the mold was completely full of plaster, it was carefully positioned upright in between three boxes, and allowed to dry for 12 hours.

Removing the plaster mold from the silicone mold through the top slit was difficult because the silicone that was imbedded with gauze did not stretch. The removal required enlarging the slit with scissors. The plaster object that was removed did not resemble the original heart that cast the mold, but was shorter and fatter, with indentations of gauze on the surface. At this point another molding process was undertaken.

The problems realized by the first prototype are as follows:

- The pig heart was not kept from deforming during the silicone molding process.
- Silicone can not be applied to the heart surface without a container surrounding the heart to hold the silicone.
- The silicone mold upon molding the plaster male replica was not held in a manner that would prevent deformation of the desired shape.

6.2 A Second Prototype Mold

With these problems realized, a second prototype was developed. The pig heart was prepared in the same manner as in the first prototype, after which the heart was stuffed with gauze to keep it from deforming, and to keep it in its expanded position (the desired position for the mold to be produced). The heart was again frozen for about 12 hours, after which it was covered with the same type of soap release agent produced for the first prototype.

A paper container was used to contain the silicone. The container measured approximately 4" (102 mm) wide by 4" (102 mm) long by 4" (102 mm) high with a wall thickness less than 1/32" (0.8 mm). Paper was selected as one of the best materials for the container, for it would allow the silicone to cure quickly by enabling diffusion of gases. The container was filled with about 2" (50 mm) of silicone, at which point the pig heart was placed into the container, and the container was filled with silicone, thereby totally emersing the heart. The container was rigid enough to sit on a flat surface during curing without deforming the mold.

The remaining mold process is identical to the previous process except that the

female silicone mold, upon being filled with plaster, was held in a manner that would put minimal pressure against the plaster, in order to eliminate deformations. This was done by attaching velcro to the mold with small screws to act as a strap that may be looped over a hook to hold the mold in mid air.

The entire process, with changes made from the first prototype, worked exceptionally well in producing a plaster replica of the heart. Several imperfections did exist due to some air bubbles and improper flow of the silicone upon molding. A light sanding with 400 grit paper smoothed any of the unwanted bumps, after which the mold was sprayed with 3 coats of polyurethane, allowing time to dry between coats. The mold was now ready for experimentation and fabricating of bladders and outer shells.

7.0 Experimentation

Much experimentation and testing was conducted on bladder materials, bladder fabrication processes, outer shell materials, and outer shell fabrication processes even before the first prototype MBAD was constructed. The following chapter discusses the work undertaken on each of these subjects, as well as a description of the construction, pumping, testing and conclusions of the first prototype MBAD.

7.1 Bladder Materials and Fabrication Processes

There are several methods that were considered for bladder fabrication processes, including a flat sheet of bladder material that is attached to the outer shell along its edges, a hemispherical sheet that is attached in the same method, two totally enclosed bladders that may be secured to the outer shell, one completely enclosed bladder that may be secured to the outer shell, and finally a completely enclosed bladder that incorporates the outer shell as part of itself. All of these methods were investigated, with attempts at producing possible pieces for experimentation. The bladder materials varied with each process, according to fabrication requirements.

An elastomeric dispersion was formed from Silastic™ medical adhesive (from Dow Corning) in order to produce flat bladder sheets. Dispersions were formed by adding the

Silastic™ to toluene, in which it dissolved easily. To produce thin flat sheets, the dispersion was cast on a flat surface, and drawn under a predetermined gap. After the dispersion was forced under the measured gap, it cured and shrunk according to how much solvent was present in the dispersion. The flat surface chosen for the experiments was glass, for which release agents were required to remove the material easily. The release agent used was a dry teflon lubricant. A metal plane (shown in figure 7.1) was designed and produced to smooth the dispersion to the correct height. The plane was fabricated from aluminum, and had a machined gap of 0.028 inches (0.711 mm). The flat bladder sheets were formed by pouring a small amount of the dispersion on the glass (which had been coated with the teflon release), and carefully sliding the metal plane over the liquid. After approximately 12 hours the elastomer is dry, and can be removed from the glass with a razor blade.

A ten percent solution and a fifty percent solution (by volume) of the elastomer were made to cast the sheets. The first membrane was 10 percent solids, and after drawing it under the 0.028 inch (0.711 mm) gap and curing, was approximately 0.003 inches (0.076 mm) thick. The fifty percent solids dispersion gave a 0.014 inch (0.35 mm) thick membrane. The membranes could be cut to the correct size, and attached, along the edges, to an outer shell (which had not been fabricated yet) using the uncured dispersion. The only unforseen problem with this process was that the material had a rather low tear resistance. This could be solved by using a different material or by adding fabric strengtheners to the material, though the latter of these solutions would not help at the seams to the outer shell.

Other alternatives for flat bladders included the many currently available sheeting materials, especially sheeting that could be heat sealed or ultrasonically welded at the edges. All options on material selection were left open due to the large availability of both polymer and elastomer materials.

The construction of a hemispherical bladder was not attempted at this point. The process would be similar in many ways to that of the flat bladder except that thickness of the material would have to be controlled solely by the concentration of solids to the

solvent. The dispersion would have to be cast on a hemispherical surface of the desired shape, possibly on the surface of the mold discussed in chapter 6, to form the bladder. One obvious dominant problem would be nonuniform surface thickness due to the gravitational flow, ie; the bladder would be thicker at the bottom edges because the dispersion would tend to flow to these points.

The fabrication of, two totally enclosed bladders that may be secured to the outer shell, one complete enclosed bladder that may be secured to the outer shell, and a completely enclosed bladder that incorporates the outer shell as part of itself, are all very similar. They all require the use of 'lost wax' techniques for which a material must be removed from inside the bladders in order to produce the enclosed bladder surface. The material must be formed into the shape of the desired bladder, and then coated with the bladder material until the desired thickness is obtained. The material must then be removed through a small opening in the bladder, for which a tube is going to attach anyways to provide the pressure required to inflate the bladder. In the case of a totally enclosed bladder that incorporates the outer shell, the outer shell material must then be applied to the outer surface of the bladder in order to form the outer shell. The latter of these cases is described in detail in chapter 8.1.

The material used in this 'lost wax' technique must meet certain requirements. It must be easily formed and altered. It must be incompatible with the bladder material in some manner to allow easy removal from the surface of the bladder, and, most importantly, it must dissolve in such a process as to not react with or damage the bladder upon removal. Two such materials that satisfy these conditions with most polymers and elastomers are gelatin and soap. These two materials may be formed into any shape by dissolving the powder in water at the appropriate concentrations. The shape may then be coated with the bladder material, and when fully cured, water may be pumped into the bladder through a small opening to dissolve the inner material. Experimentation on this process was limited to later in the MBAD fabrication process (see chapter 11).

7.2 Outer Shell Materials and Fabrication Processes

The development of the outer shell relied on the plaster replica of the heart (discussed in chapter 6) for size and shape, independent of the shell material. Outer shell materials had to be considered according to whether the shell was to be rigid or flexible. In the early experimental stages, medical sterility, and human compatibility were ignored to allow the mechanics of each configuration to be easily tested.

For the fabrication of a rigid shell, experiments were conducted with acrylic plastic and polyester resins (epoxy) that were easily attainable. At this point in the development process, the fabrication of a flexible outer shell was considered by coating the heart replica with a flexible, nonextensible material, and then removing the shell when cured, though this was not tried until later (see chapter 8).

Acrylic, with a thickness of 1/16 inch (1.58 mm) was heated over an electric heating coil until the plastic became very malleable. Then, using insulated gloves it was pressed over the plaster mold in order to form one half of the shell covering one ventricle, and then cooled back to a rigid form with an air conditioner. Upon cooling, the material would assume the position at which it was held with very little hysteresis. The major drawback with the result is that the acrylic would wrinkle in order to form into the desired shape. This could be avoided if the material were to flow into position by melting, but this was unattainable without the acrylic igniting.

For a polyester (epoxy) and fabric shell to be produced, the surface of the heart replica was coated with a layer of plumbing clay to act as a release. A thin dacron fabric was cut into 1 inch (25.4 mm) by 2 inch (50.8 mm) squares to be used as reinforcement. A layer of fabric was applied to one half of the heart replica opposite one of the ventricles, and the polyester resin mixed with appropriate amounts of hardener as required by the directions was applied with a spatula to cover the fabric. This process of alternating fabric and resin was continued in order to form a shell of about ten layers. The shell was allowed to cure for 24 hours, at which time much of the resin had run off the fabric before it had cured. Removal from the mold was very difficult, for the resin had in some way reacted with the clay so that it would not release. After a very slow removal process, the shell was

removed and it was observed to be too shallow to provide a good retainment for a bladder. At this point, enough experience had been gained to design and fabricate a complete MBAD using the techniques that had been developed and experimented with.

7.3 The First Prototype MBAD

It was decided to construct and test a prototype of the pneumatic bladder- actuated MBAD to determine the effectiveness of this type of actuation system. It was decided to construct it with a rigid shell, and with a flat, nonextensible bladder, for this would be the easiest to fabricate at this point. The problems that were discovered in the previous testing, and that had to be solved, were:

- The outer shell would have to be made so that each half of the shell could completely enclose a bladder to pump one ventricle.
- The material from which the shell would be fabricated must be thick enough not to run off the fabric reinforcement.
- The bladder material must be tear resistant, and easily sealed to the outer shell.
- A method of attaching the tubing to the bladder that does not affect the pumping mechanism must be developed.
- A method of holding the two half shells together, including adjustment, must be developed.

7.3.1 Fabrication

In order to fabricate a shell in which both sides mated together, it was decided to construct the shell as a continuous piece over the entire replica mold, and to cut the shell in half in order to remove it from the mold. A thick polyester resin paste was selected as the best material for the outer shell. A thin sheet of metalized Mylar® was selected for the bladder, due to good tear resistance and availability.

The shell was fabricated in a similar manner to the polyester shell discussed in chapter 7.2. The plaster heart replica was coated with a thin layer of plumbing clay about

1/4 inch (6.35 mm) thick) and a layer of dacron fabric consisting of 1 inch (25.4 mm) by 2 inch (50.8 mm) pieces was layed over the clay in order to completely cover the mold. A thin layer of the polyester paste, mixed with hardener according to the directions, was spread over the dacron with a spatula, covering it completely. This process of alternating fabric and polyester resin was continued in order to form a shell of about ten layers. The shell was allowed to cure for 24 hours, at which time it was cut in half lengthwise with a 1 1/2 inch (38.1 mm) diameter emory saw attached to a Dremel™ motor tool, rotating at 30,000 rpm. Care was taken not to touch the plaster, but only to cut into the clay through the outer shell. The shell was easlily removed from the mold, though some clay had to be cleaned off the interior of the shell with the edge of a knife.

The Mylar® sheet to be used as the bladder was measured and cut to a size for which its edge could be sealed to the edge of each half of the shell. Epoxy was used to attach it to the shell's inner edge. When the epoxy had cured, a thin layer of silicone adhesive was applied over the edge of the bladder to additionally seal it to the shell. Tubing attachments to each bladder were made by drilling through the outer shell and threading a brass fitting into the shell, for which standard 1/4 inch (6.35 mm) (1/8 inch (3.2 mm) ID) tygon tubing could be attached.

The two half shells were connected together to form the total enclosure by means of velcro. This would enable tightening or loosening the enclosure on the heart by means of adjustmenting the velcro. The hooked side of the velcro was attached to one of the half shells along its outer surface by means of epoxy. The other side of the velcro (containing the loops) was attached to the opposite shell so that it could connect to the hooked velcro when the two half shells were mated together to form an enclosure. The adjustment of the velcro could accomodate from zero clearance between the two half shells to about 1 inch (25.4 mm) clearance. The completed prototype is shown in figure 7.2.

We wanted to use only one pump to actuate both bladders simultaneously, so the two tubes, each connected to a bladder, were connected to a 'Y' fitting, for which the single remaining tube connected to a large bellows foot pump. The pump was altered slightly by removing the outlet check valve and blocking the inlet check valve. This

modification enabled a closed pumping system to exist in which all air pumped into the heart bladders when the pump was compressed would be evacuated when the pump was able to expand by means of an internal spring. The bellows pump is shown in figure 7.3.

Upon completion of the prototype and pumping system, a pig heart was prepared according to the procedure discussed in chapter 2, and connected to the heart test stand as shown in figure 2.5. The heart was enclosed in the prototype, which was tightened with the velcro straps. The top of the outer shell opposite the atrium was trimmed slightly to allow the atrium to protrude from the shell. Using the bellows pump, air was pumped into the prototype, which expanded the bladders, applying force to the outer walls of the heart, and compressing both of the ventricles simultaneously.

The right ventricle, with its thin wall, compressed rather easily and pumped water out with each compression. The left ventricle, with a much thicker wall, did not compress easily, and no conclusions could be made of its pumping efficiency due to bladder forces. Increasing bladder pressures by applying more pressure to the bellows did not increase heart pumping output, but rather pushed the heart out of the prototype enclosure. Even by holding the heart within the shell, pressures could not be applied to pump the left ventricle extensively. The dominant reason for the lack of ability to pump the left ventricle is the hardening of heart tissue, as discussed in chapter 2.1.3.

8.0 The Development of a Dipping Machine

Before the development of a dipping machine can be discussed, it is important to discuss why a dipping machine is necessary to the MBAD fabrication process. This requires, first, an explanation of the conceptualized fabrication process.

8.1 The Conceptualized MBAD Fabrication Process

The most reliable bladder actuated MBAD is a one piece design in which the bladder incorporates the outer shell as part of itself (as refered to in chapter 7.1). This requires the outer surface of the bladder to be inextensible, as well as geometrically equivalent to the heart surface so that an accurate fit of the MBAD on the heart may exist.

A simple and efficient method for producing this is to coat the entire plaster heart mold with the bladder material to the desired thickness. The areas where the bladder is to be expanded are then coated with a masking material that adheres to the bladder, but can be easily and entirely removed. The entire mold may then be coated with the outer shell material, which must chemically dissolve and bond to the bladder material where the bladder has not been masked. The masking material may then be removed through a small slit in the outer shell directly over the bladder. This slit may then be used to attach the tubing to the bladder.

8.2 Selection of the Optimum Coating Process

The coating of the plaster mold for the fabrication of both the bladder and the outer shell can be done by spraying or brushing the material onto the mold, or by dipping the mold into the material. Due to the difficulty in producing a uniform coating by means of brushing, this technique was not considered. Due to the complexity in spraying uniform coatings with varying material viscosities and the hazards associated with spraying materials containing dangerous solvents, it was decided that the dipping of the mold into the bladder and outer shell materials would be the optimum fabrication technique.

8.3 The Purpose of a Dipping Machine

A dipping machine is a device that enables the mold to be held and cyclically dipped into the polymer dispersion to apply a coating to the mold. The application of many overlapping coatings produces a homogeneous polymer layer of the desired contour.

As the viscosities of bladder and shell materials are varied, the number of dipping cycles will change in order to produce the same thickness coating, ie, the lower the viscosity, the more dipping cycles required. Materials with lower tear resistance will require more coatings than materials with higher tear resistance for equivalent tear strengths (assuming equivalent viscosities). The manual dipping of the mold to accomodate the testing of these parameters with different materials is inefficient, due to the numerous dipping cycles required. It is also important that the mold be entered into the material at

precise speeds, that the duration of the mold in and out of the material is constant, and that the position that the mold enters the material is fixed. These aspects all lead to the concept of an automatic dipping machine, for which speeds, times, cycles, and mold positioning can be controlled.

8.4 Design of the Automatic Dipping Machine

The design of an automatic dipping machine was directed by the operating features that were required for the machine to be useful. As stated earlier, the machine had to be capable of controlled dipping speeds, dipping and drying times, and mold positioning. Due to the solvents present in the coating materials, the machine had to be capable of evacuating the fumes from the area.

The desired dipping motion consists of a downward action of the mold into a container of the coating material. When the mold has been coated to the desired depth, the mold is returned upward to its original position. The two different actuating methods that were considered were a motor driven linkage (or cam), and a pneumatic piston. The pneumatic piston actuation method was decided to be the optimum choice due to its flexibility in changing upward and downward speeds easily by the alteration of flow rates (the motor would be required to change its speed via an electronic control system). The disadvantage of the pneumatic system is that it required a source of pressurized gas, as well as the electronic control.

A schematic of the dipping system is given in figure 8.1, for which the electronic timing control is shown in figure 8.2. The dipping action is produced by the gravity feed of the piston as the three-way (normally open) solenoid valve is closed (energized). The piston downward speed is controlled by a needle valve on the upper port of the cylinder. If a quicker downward motion is desired once the needle valve is in its fully open position, additional weight can be added to the piston where it connects to the mold. The mold is connected to the piston by means of a threaded coupling for which the piston shaft screws into one half, and a threaded rod imbedded in the plaster mold screws into the other half. The return motion of the piston is caused when the solenoid valve is opened (de-

energized), which allows the cylinder to pressurize, thus forcing the piston upward against its gravitational force. Upward speeds may be adjusted by both a needle valve on the incoming gas and a pressure regulator on the gas. The pressurized gas is provided by a small cylinder of compressed freon 12. The original cylinder is still in operation after providing more than 1000 dippings.

The dipping cycles are controlled by a recycling timer that energizes the solenoid valve by means of a relay. The recyling timer is an original design that utilizes two timing integrated circuits. One integrated circuit controls the duration between cycles, and the other integrated circuit controls the duration of each dip. The circuit that controls the duration between cycles is used to trigger the other timer, which energizes a relay for the duration of its cycle, after which it turns off. The relay acts as a switch for powering the solenoid valve.

The timing cycles are controlled for each timer separately. The timer controlling the duration between cycles is a programmable timer that utilizes a binary input to determine the timing cycles. A rotary switch connected to these inputs enables the selection of different duration times. The times preset correspond to 1 minute, 2 minutes, 4 minutes, 8 minutes, and 16 minutes. The timer controlling the duration of each dip utilizes a varying resistance to change its duration time. This is also controlled by a rotary switch that selects different resistances to change the timing. The times preset correspond to 1s, 2s, 4s, 8s, 10s, and 30 seconds. The preset times for each timer can be easily changed by some simple re-wiring.

Three switches are provided in order to control power to the timers, power to the solenoid valve, and manual triggering. When power is provided to the timers, they automatically trigger and start the dipping cycles. The power to the solenoid valve may be controlled so that the timers may function without performing the dipping operation. Manual triggering is necessary if a dip is desired at a time when the timer controlling the duration between cycles is in between cycles. This action does not disturb the timing cycle, but provides a manual signal to activate the timer that controls the duration of each dip. The signal is similar to the signal automatically generated by the timer that controls the duration

between cycles.

The dipping machine, shown in figure 8.3, was constructed from wood, with glass enclosing the dipping area for ease of visibility. A fan is mounted at the top rear panel of the machine to exhaust fumes into a chemical hood. The timing controls are mounted in the front of the machine above the dipping area. A push button switch is provided to control power to the exhaust fan, and a light mounted in the dipping chamber. The air cylinder, which provides the dipping motion, is mounted vertically in the middle of the machine, for which the piston shaft may travel from the top to the bottom of the dipping chamber.

9.0 Dipping- A Determination of Materials and Technique

Much experimentation was required to determine the optimum materials and the optimum process for which to use these materials, in order to form a strong, homogeneous coating. The determination of the optimum technique involved altering material viscosities, solvent systems (in order to change evaporation rates), the duration of both dipping and drying times, and the number of dipping cycles. The first consideration was to develop a suitable dipping material.

9.1 A Suitable Dipping Material

A polymer/elastomer dispersion in a solvent was the principle method undertaken for determination of an appropriate material, though silicones were also investigated. The dipping materials were required to be very soluble in hydrocarbon solvents (toluene, methylene chloride, cyclohexanone, tetrahydrofuran, etc.), and to cure at room temperature with little or no residue resulting from the solvents.

The first material obtained was claimed to be a polyester elastomer which would be easily dissolved in most hydrocarbon solvents. The material was obtained in rod form, so it was necessary to grind the rod into a powder for ease of dissolving. This was accomplished by means of a wire brush wheel attached to a drill, with which the material was easily ground into a fine powder. About five grams of this powder was then added to about 100 ml (3.38 ozfl.) of different solvents. The different solvents were toluene,

methylene chloride, (1,4) dioxane, ethyl acetate, and methyl ethyl ketone. Each container was shaken and then left to sit. After approximately 12 hours, the containers were checked, and it was found that not one of the solvents had dissolved the powder, to even the slightest amount. It was later found that the polyester obtained had been cross linked, disabling its solubility in the solvents used.

A polyester elastomer, Hytrel®, was obtained from E.I. duPont de Nemours and Company, in a powdered form (see appendix II for material specifications). Methylene chloride was the recommended solvent, in which it dissolved almost instantly. A 4 liter (1.05 gal.) nalgene container was used to hold the dispersion. The dispersion was made from 2 liters (0.52 gal.) of methylene chloride, and about 200 ml (6.76 ozfl.) of the Hytrel® powder. The dispersion was very volatile (see appendix I for chemical specifications), and the surface would cure in seconds when the container lid was removed. It was therefore evident that a means of sealing the dispersion from the surroundings was required between dippings. In order to avoid excess machinery and control by using a retractable lid, a layer of distilled water was added to the dispersion, which remained at the surface (because of its lower density), thus eliminating any evaporation of the dispersion. This was possible not only because of the densities of the two materials, but also because of the lack of solubility between the two materials.

9.2 Preparation of a New Mold

The heart replica mold previously used to fabricate the first prototype MBAD was ruined beyond repair by the putty and epoxy used, so another mold was made (in the manner discussed at the end of chapter 6). A threaded rod was attached to the mold by drilling into the top of the mold and inserting the rod. Epoxy was used to secure the rod. At this point, the mold was sprayed with polyurethane. The mold, after being coated with polyurethane, was coated with four layers of silicone. This was done in order to act as a release agent for the dipping process. The mold was coated with silicone by first dissolving Silicone II® in toluene at 25% solids. This solution was then sprayed onto the mold by means of a spray container. The spray container was filled with the

silicone/toluene dispersion, and then pressurized to 60 psi with an air compressor. A spray nozzle on the container allowed the dispersion to be sprayed as a mist onto the mold, similar to that of a can of spray paint. Upon curing, the mold was attached to the dipping machine via the threaded rod, and was ready to dip.

9.3 A Month of Dipping

A little over a month was spent dipping the heart replica mold into either the Hytrel™ dispersion or a silicone and toluene dispersion. Different releases on the mold were tested, as well as different dipping cycles, duration times, and drying times.

For the first dipping, the machine was set to dip at 2 minute intervals with a dip duration of 4 seconds. The mold was dipped twenty times into the Hytrel® dispersion through a layer of distilled water. The mold coated (wetted) very nicely, but upon drying, shrank due to the evaporation of solvent, and the coating tore away from the mold. This got continually worse as the number of dips increased. After the twenty dips, the torn shell was removed from the mold.

The mold was dipped again into the same dispersion with the machine set to dip at 10 minute intervals with a dip duration of 4 seconds. The mold was dipped 33 times. The coating reacted as before, tearing off the mold upon drying. The coating upon removal was worse than the previous attempt.

The mold was covered with a layer of common plastic wrap (used to cover food), and was shrunk to a precise fit by heating it over a burner (equivalent to this would be the use of a hair dryer or hot air gun). A wire was tightened around the top of the plastic wrap to ensure that it would not peel off. The dipping machine was set to dip at 4 minute intervals with a dip duration of 4 seconds. The mold was dipped fifty three times into the Hytrel® dispersion through a layer of distilled water. The shell was removed from the mold by peeling and rolling the material downward. The Hytrel® had securely bonded to the plastic wrap so that the plastic wrap was part of the shell. The shell (shown in figure 9.1) was inextensible, though not extremely flexible due to the hardness of the material (for an elastomer).

The machine was set to dip at 2 minute intervals with a dip duration of 6 seconds. The mold, again covered with the plastic wrap in the same way as before, was dipped twenty eight times into the Hytrel® dispersion through a layer of distilled water, after which another layer of plastic wrap was attached directly opposite both ventricles. This layer was to act as a mask over both ventricles in order to form the bladders. The mold was then dipped sixteen more times with the same machine settings. The shell was removed in the same manner as the last shell, and the separation of both bladders from the outer shell was attempted. Apparently, the dispersion had diffused under the plastic wrap mask, embodying the plastic wrap into the shell. The shell is shown in figure 9.2.

The mold was again coated with plastic wrap using the same preparation method, and dipped ten times with the machine set to dip at 4 minute intervals with a dip duration of 6 seconds. A gelatin solution was then made at five times the recommended concentration, and allowed to cool to the point that it could be applied over the shell, which was still on the mold, as a putty. This was applied directly opposite the ventricles again to act as a mask for the bladders, with a thickness of about one quarter of an inch (6.35 mm). The mold was then dipped again, at which time the left mask fell off the mold on the first dip. The mold was dipped a total of twenty six times, not coating very well over the gelatin, and on the last dip, the right side mask fell off. The shell (shown in figure 9.3) was removed from the mold, with neither bladder intact.

It was desired to produce an extensible bladder, for this would avoid wrinkling of the bladder in the relaxed position (as discussed in chapter 5). The use of the Hytrel® dispersion would not enable this, so a dispersion of silicone and toluene was used. The silicone dispersion could not be used for an outer shell due to its extensibility, so the use of Hytrel® could be used for this. The problem was that the Hytrel® and the silicone were not compatible, and would not adhere to each other. An attempt was made to see if the Hytrel® would adhere to an uncured silicone dispersion by brushing the silicone onto the plastic wrap coated mold and then dipping the mold into the Hytrel® dispersion, but again the materials did not adhere. It was observed at this point that the silicone did not adhere to the

plastic wrap as well.

A silicone bladder and shell were made by dipping the plastic wrap coated mold into the silicone dispersion with the machine set to dip at 10 minute intervals with a dip duration of 4 seconds. The bladder was dipped a total of eight times, after which plastic wrap was placed opposite the two bladders to act as a mask between the bladder and the outer shell. The mold was dipped twenty two more times with the same machine settings, after which the unit was removed from the mold, and the two bladders were separated from the outer shell. The device (shown in figure 9.4) was unacceptable due the fact that the outer shell was extensible, though it showed that the most feasible method for producing the MBAD would be to use a common material for the bladder and the outer shell that could be adjusted to account for the extensibility properties between the two sections.

An understanding had been obtained of the dipping technique as well as the desired material properties. It was seen that a longer drying time produced a better coating, with minimal duration of the dip, allowing the mold to enter the dispersion slowly to avoid any cavitation, causing air bubbles. One dip in the solutions used produced about a 0.001 inch (0.0254 mm) coating thickness after drying. Depending on material properties, at least ten coatings is required for a strong, reliable layer. Another important factor on the dipping process was the covering of the dispersion in between dippings. Distilled water was used for the Hytrel® mixture, which worked rather well. The silicone dipersion, on the other hand, reacted slightly with the water, causing some of the silicone on the surface to cure. This precluded the use of water, and required the covering of the mixture in between dippings. Thus, a material that could be coated while dipping through a liquid barrier, whose properties could be adjusted to provide an extensible bladder and inextensible shell, was sought.

10.0 Mansfield Scientific

Mansfield Scientific Inc. was visited in order to observe the fabrication process of the intra-aortic balloon pumps, which are fabricated from a polyurethane material by

dipping. The generalities of the process will be discussed.

10.1 The Fabrication Process

Gelatin and water are mixed at the correct concentrations and injected into several female silicone molds shaped like the inner surface of the intra-aortic balloon pumps.The outside of the molds are cooled until solid, and then the molded gelatin pieces are put inside an automatic dipping machine. The machine is about ten feet (3 m) by five feet (1.5 m), not including a computerized controller that sits independently on the floor. The machine is capable of controlling the dispersion temperature and viscosities as well as drying temperatures of the dipped pieces. All timing cycles are independently adjustable, with the machine capable of terminating at any instant. The dispersion is kept in a closed container, except during dipping, in which a lid on the container is automatically removed, after which the lid is returned. A vacuum attached to the dispersion container keeps the lid tight. All fumes are exhausted from the machine, out of the building.

The molded gelatin pieces are dipped by the dipping machine into the polymer dispersion, and are allowed to dry in between dips inside a heater. When the dipping process is completed, the pieces are removed from the dipping machine. Warm water is pumped into the pieces in order to remove the gelatin, and the pieces are allowed to dry overnight. A completed intra-aortic balloon pump is formed by attaching the tubing to the urethane piece.

11.0 Development of the First Urethane MBAD

It was discovered that a common dipping material is a mixture of Polyurethane Estanes from BFGoodrich (Specialty Polymers & Chemicals Division) in a mixture of Cyclohexanone and Tetrahydrofuran (THF) solvents (see appendix III for the exact formulations). During dipping, the urethane is usually kept at 55-59℉ (12.8-15℃) with a viscosity of 56-50cp. The flashpoint of the dispersion is controlled by the addition of cyclohexanone to the THF. The addition of cyclohexanone increases the flashpoint, eliminating any possible pin hole leaks that may be formed in the urethane during drying

by too low a flashpoint.

The Estane Polyurethane resins available from BFGoodrich range from hard to very soft, with compatible solubilities, enabling very versatile hardnesses. They are suitable for producing a part that encompasses an extensible bladder with an inextensible shell. The disadvantage of the solvents used is that they react with water, precluding the use of a water barrier to prevent the evaporation of the dispersion.

Samples of the Polyurethane Estanes were ordered from BFGoodrich, and Cyclohexanone and Tetrahydrofuran (THF) were obtained from the Chemistry Department. The Estane samples ordered for the outer shell were the same as those used for the intra-aortic balloon pump, and they would be mixed in the same ratios (see appendix II & III for these ratios and material properties). The Estane ordered for the bladder was a softer urethane, with over 50% increase in elongation (see appendix II for the material properties).

Before an actual MBAD was developed, dipping tests of the urethane dispersions were conducted in order to experiment with the release from gelatin coatings, as well as the mechanical properties of the material. Different temperature configurations of the material and the drying chamber were also tested.

11.1 Urethane Coating Testing

11.1.1 Test 1

The plaster heart mold was covered with an ordinary large rubber balloon that was in turn coated with two coats of gelatin. The balloon was used as a smooth cover to eliminate many of the indentations and irregularities on the heart mold, as well to act as a carrier of the gelatin coating. The gelatin solution was formed by mixing regular unflavored gelatin with boiling water at 2 1/2 times the proper concentration. The solution was applied to the balloon covered mold with a foam brush, and allowed to dry in front of an air conditioner for 5 minutes before applying the second coat. The gelatin dryed as a hard shiny shell, unlike the rubbery form usually associated with gelatin when water is present.

The urethane material for dipping was kept in a stainless steel container during the entire dipping process. Attached to the container was a digital thermometer to read the temperature of the material (see Figure 11.1). The material at Mansfield Scientific was kept below 55℉ (12.8 ℃), so the coating was cooled by the air conditioner before dipping. A heater coil was also attached inside of the dipping chamber with a thermostat that could maintain an 80℉ (26.7 ℃) temperature during drying of each coating.

The urethane material for the bladder was cooled in the stainless steel container to 65.7℉ (18.7℃). The gelatin coated heart mold was at room temperature, which was approximately 74℉ (23.2℃). The mold was dipped with the automatic dipping machine for 5 seconds into the urethane and then removed to dry for one half hour (the lid on the stainless steel container was removed before the dip and replaced after to keep the solvents in the urethane mixture from evaporating). During the dip, the gelatin cracked all over, so on the following dip, the urethane, in addition to coating the gelatin, coated the rubber balloon in between the cracks. This was undesirable, because it was feared that the urethane could not be removed from the balloon. The dipping process was terminated and the coating was allowed to dry over night. It was concluded that the cracking of the gelatin was due to the temperature differences between the coating and the mold. The gelatin coating was very brittle, so any small deformations caused by a temperature change could easily produce cracks. The dried coating and balloon were removed from the mold, and then the coating was removed from the rubber without significant difficulty by soaking in warm water. This indicated that the removal of the urethane from the rubber balloon was possible.

11.1.2 Test 2

The mold covered with another rubber balloon (not coated with any gelatin) was dipped into the bladder urethane material at 65.7℉ (18.7℃) for five seconds, and then allowed to dry for one half hour, after which it was dipped again into the urethane without stopping. The mold was dipped a total of 9 times, with a drying time of one half hour between dippings. After the urethane had dried overnight, gelatin was dissolved in boiling

water 1 1/4 times the correct concentration, to be applied as a mask for the bladder. Four drops of red food coloring were added to the gelatin solution to improve visibility of the originally clear gelatin on the urethane surface. Three coats of gelatin were applied to the bladder surface opposite each ventricle on the mold, as well as a small passage connecting each bladder mask. This small passage of gelatin would act as a mask for the through passage of gas to flow from one bladder to the other so that an outer tubing connection would only have to be made to one bladder. The gelatin was applied to the urethane bladder with a foam brush, and allowed to dry in front of an air conditioner for 5 minutes before applying the second coat. The same was done to the second coat before the third coat was applied. It should be noted that the gelatin solution was kept at the verge of boiling during the entire gelatin application process, causing the solution to thicken for each additional coating.

The gelatin masked, urethane coated, heart mold was dipped into the outer shell urethane material for a duration of five seconds, keeping both the urethane and the mold at room temperature 74.1℉ (23.4℃) (the mold was allowed to warm to room temperature for 1 hour before dipping), and allowed to dry for one half hour. It was dipped 9 more times without stopping the mold while in the urethane, with a drying time of one half hour between dippings. After thoroughly drying overnight, the balloon and urethane coating were removed from the heart mold. Attempts to remove the urethane from the rubber was not successful. A small slit was cut into the outer shell and the entire unit was soaked in warm water to dissolve the gelatin separating the bladder material from the outer shell. This worked perfectly, allowing the bladder to be a completely separate layer from the outer shell. The bladder upon stretching was very extensible, but lacked excessive tear strength, so it was decided to combine the bladder material with the outer shell urethane material in a 50% ratio to increase the tear strength of the bladder (this would also decrease the extensibility of the bladder material).

11.1.3 Test 3

The heart mold was again covered with a rubber balloon, and then coated entirely

with 4 layers of gelatin in a similar manner to the gelatin produced to mask the bladders of the previous urethane shell in test 2, except that food coloring was not added, for it was not necessary. The mold was dipped into the urethane mixture of 50% outer shell material and 50% bladder material for a duration of five seconds, keeping both the urethane and the mold at room temperature (75.4℉ (24.1℃)), and allowed to dry for one half hour. It was dipped 9 more times without stopping the mold while in the urethane, with a drying time of one half hour between dippings. After allowing to dry overnight, the urethane bladder was removed by soaking the mold in warm water while removing the rubber balloon. The gelatin dissolved easily between the rubber and the urethane, allowing the bladder to be removed. The wet bladder was dried, and elongated by hand in order to determine the extent of elasticity. It was determined to be elastic enough not to plastically deform when inflated, and was extremely tear resistant, so another MBAD was constructed using this urethane mixture for the bladder.

11.2 Fabrication of The First Working Urethane MBAD

The plaster mold was covered with a rubber balloon and then coated with 4 layers of gelatin in a similar manner to tests 2 & 3. The mold and the urethane bladder mixture were allowed to warm to room temperature (76.1℉ (24.5℃)) for 1 hour, after which the mold was dipped 10 times in the urethane in a similar procedure to tests 2 & 3. The urethane was allowed to dry overnight, after which a mixture of gelatin was made as before, except that five drops of green food coloring were added to enable visibility of the solution over the bladder. Four coats of gelatin were applied opposite each ventricle in a similar manner to test 2, in order to mask the bladders and tubing connections in the appropriate areas. The green food coloring worked well, enabling each gelatin coat to be easily located.

After allowing the gelatin to completely dry and the mold and outer shell urethane material to warm to room temperature (77.5℉ (25.3℃)), the mold was dipped 12 times in the outer shell urethane in a similar manner to tests 2 & 3. When completed, the urethane was allowed to dry overnight, after which the mold was soaked in warm water and the

MBAD was removed from the rubber balloon. A small slit was made in the outer shell directly over the left bladder similar to that done in test 2, and the gelatin was removed from between the shell and both bladders and connecting passages. A Teflon® lubricant (Teflon dispersed in a weak solvent) was used to flush the bladders in order to avoid the bladders adhering to the shell. A thin Teflon® film is all that remained on the interior of the bladder after the solvent evaporated.

Tygon tubing was attached to the left MBAD bladder by inserting the tubing into the slit used to remove the gelatin and to flush the bladders with teflon, so that the tubing protruded into the outer shell by about 1/16" (1.58 mm). A paint brush was then used to 'paint' a layer of the outer shell urethane material onto the seam between the tubing and the outer shell. This was done a total of ten times, allowing the layer to dry for ten minutes between each coating. When this was finished the completed MBAD (see figure 11.2) was allowed to dry overnight before it was to undergo testing.

12.0 The Development of a Pumping Machine

In order to test the urethane MBAD, a system to provide the pneumatic pumping action was required (see figure 12.1). The pump would inflate the bladders with gas at the proper pressure in the correct volume for each timing cycle. The timing cycle would correspond to the physiological pumping cycle (an average of about 70 beats per minute). For display purposes it was desired to have the pumping unit portable. This chapter will describe the components and fabrication of the pumping system.

The pumping system (shown schematically in figure 12.2) consists of a cylinder of compressed liquid freon that expands through a pressure regulator into a coil of copper tubing with outflow governed by a solenoid valve controlled by a timing circuit. The cylinder of liquid Freon contains 354.8 ml (12 ozfl.) of Freon 12, which corresponds to approximately 44,000 ml (1487.8 ozfl.) of atmospheric freon gas (230 pumps of 140 ml (4.73 ozfl.) volume at 5 p.s.i. (34473 Pa)). The pressure regulator regulates the freon from a gas pressure of about 100 p.s.i. (0.69 Mpa) to a pressure between 0 and 30 p.s.i. (0 - 0.2 Mpa) depending on the adjustment on the control knob. The coil of copper tubing

is used to warm the expanding gas slightly between cycles. A solenoid valve is connected to the end of the coiled copper tubing. The solenoid valve is a three way normally closed valve that opens upon actuation with 24 volts, enabling the freon gas to flow into the bladders of the MBAD. Disconnecting the power to the valve closes the valve, enabling the gas that was pumped into the bladders to flow out and into the atmosphere.

The electronics that control the solenoid valve consist of a battery supply of two twelve volt lattern batteries that are connected in series to provide a 24 volt supply source for the solenoid valve. A main power switch allows power to be supplied to a digital repeating timer (from Artisan Timers Inc.). The timer is connected with two ten- turn potentiometers that vary resistance to the internal circuitry of the timer in order to adjust the pump duration time and the repeat cycle time. Upon triggering at the beginning of each repeat cycle time, the timer provides a voltage to actuate a relay for as long as the pumping duration time. The relay, connected in series with an exterior toggle switch (which allows on or off control of this voltage), acts as a switch between the battery supply and the solenoid valve; when the relay is actuated, the solenoid valve is actuated. An additional external toggle switch is provided to manually trigger the solenoid valve.

The entire pumping system is contained in a 12" (30.5 cm) by 12" (30.5 cm) aluminum box with a handle for ease of portability. All controls are provided on the exterior of the container. In addition to the controls are two lights to indicate power and the solenoid valve actuation. A counter is also provided that indicates the number of times the system has pumped (which may be reset by depressing a pushbutton). The top of the box may be opened, and a stand is attached to hold the MBAD in the pumping position for demonstration purposes.

13.0 MBAD Testing

Using actual pig hearts, water was pumped through the physiological test stand discussed in chapter 2, with the MBAD actuated by the pumping system. This enabled conclusions to be made of the MBAD's ability to pump and remain on the heart. The testing process will be discussed, as well as a new preparation method for the pig hearts,

conclusions for a new heart mold, and the description of a new physiological test stand.

13.1 Preparation of the Pig Hearts for Pumping

The pig hearts that were obtained from the butcher required preparation before they could be attached to the physiological test stand, as discussed in chapter 2. The previous method used was quite tedious and time consuming due to the intricacy involved. A new process of attaching fittings to the appropriate veins and arteries, as well as closing undesireable holes, was developed in order to eliminate these problems.

Aluminum fittings were machined that would fit snuggly into the aorta, pulmonary artery, venae cava, and pulmonary vein (see figure 13.1). The fittings consisted of a 3/4" (19 mm) diameter grooved cylinder to fit into the heart, stepped down to a 1/2" (12.7 mm) diameter grooved cylinder to fit the inner diameter of the tygon tubing. Stainless steel stepless ear clamps, 7/8" (22.2 mm) diameter, obtained from Oetiker, Inc. (shown also in figure 13.1) were used to clamp the aluminum fittings to the proper vein or artery by positioning the clamp around the vein or artery while inserting the fitting inside. Squeezing the ear on the clamp with pincers tightens the clamp with a 360° seal around the vein or artery.

The heart is prepared in a similar manner to chapter 2 by cutting excess tissue that is attached, and then removing the aortic arch so that the aorta protrudes from the heart by about an inch. The pulminary artery and both veins are cut to protrude from the heart by about an inch as well. The fittings are attached using the ear clamps. Any small openings in the heart are closed using thread, as before. If desired, these openings may also be closed by the ear clamps used to attach the fittings, by placing a clamp so that it squeezes the opening closed as it is tightened.

13.2 Pumping the Pig Heart

Tubing from the physiological test stand was attached to the fittings on the heart, and with the tubing clamps on the tubing attached to the test stand closed, the stand was filled with water. The MBAD was slipped over the heart, and the tubing clamps on the

tygon tubing were opened, allowing the heart to fill with water. The heart expanded upon filling to completely fill the MBAD (for which it was already a pretty close fit), and then continued to expand above where the MBAD covered the heart, causing the atrium to bulge out significantly. The MBAD pumping system was turned on, which caused the bladders to fill with compressed freon at about 4 p.s.i. (27,579 Pa). The bladders compressed the ventricle walls of the pig heart extremely well, forcing water back out the vena cava and pulmonary veins, which indicated that the mitral and tricuspid valves were not functioning correctly. A second actuation of the bladders caused the heart to slip out of the MBAD, indicating that the bladders were providing an upward force to the heart. All the while, slight leakage of the aortic and pulmonary valves was causing the level of the right and left pressure cylinders on the test stand to lower into the inlet cylinders.

In conclusion, the testing produced several ideas for advancement. They can be listed as follows:

- A new mold is required for producing the MBADs, because the MBAD needs to extend higher up on the heart in order to keep the atrium from overexpanding, as well as enabling the bladders to be placed so that they may retain the heart better. The entire mold will be dipped to provide a section on the top of the mold that may be formed into a strap to additionally retain the heart. The mold will be coated with a release agent that will eliminate the use of rubber balloons and a gelatin coating to release the MBAD from the mold.
- A new test stand is required that will more closely mimick the physiological change in pressures of the cardiac cycle, as well as replace all of the valves required in the heart. The test stand will be a closed system equivalent to the human body, which may be pumped continously for testing the MBADs durability in prolonged usage.
- New MBADs must be produced from the new mold with bladders that do not push the heart upward. A retaining strap on the top of the MBAD will also help to retain the MBAD on the heart.

14.0 Development of a New Physiological Test Stand

A new heart test stand was desired that would closely mimick the physiology of the human cardiac system in terms of dynamic pressures and flows. The test stand was to function in a similar manner to the previous test stand, providing the pig heart to be tested with realistic inlet and outlet pressures, as well as flow volumes. The main changes that were made are that the new stand is a closed system, responds with dynamic pressures and flows similar to that of the human body, contains the required check valves to eliminate them internally from the pig heart, and is a self-contained portable unit.

Being a closed system, the test stand allows continuous pumping of the heart without having to be refilled with water (water is recirculated through the test stand). Instead of the heart pumping into a constant pressure, as in the original test stand, the new stand allows the pressure to increase from a cracking pressure (the pressures at which the aortic and pulmonary valves begin to open) to a maximum pressure during the proper volumetric flow. This will be discussed in more detail in the following paragraphs. The valves inside of the pig heart may all be removed, eliminating the possibility of faulty valves, for check valves are installed in the appropriate positions in the test stand. By creating a system of springs and diaphragms, the use of columns of water is eliminated, allowing the unit to be small enough to be self-contained and portable.

The design and fabrication of the test stand will be described, as well as the theoretical determination of variables, and finally the calibration process. Before it was possible to design the test stand, all of the physiological parameters were determined. These parameters are discussed in the following paragraph.

In the human cardiac cycle, the left and right sides of the heart can be considered as two different systems with different dynamic pressures. The left side of the heart, which pumps blood through the body, is the high pressure side. During systole, the aortic valve opens at 80 mm Hg (42.8" H_2O), and the pressure in the aorta builds up to 120 mm Hg (64.2" H_2O) as about 70 ml (2.37 ozfl.) of blood is pumped from the left ventricle. The right side of the heart, which pumps blood through the lungs, produces much smaller

pressures. During systole, the pulmonary valve opens at 8 mm Hg (4.3" H_2O), and the pressure in the pulmonary artery builds up to 25 mm Hg (13.4" H_2O) as about 70 ml (2.37 ozfl.) of blood is pumped from the right ventricle. During diastole, the left atrium fills at about 8 mm Hg (4.3" H_2O), and the right atrium fills at about 1-5 mm Hg (.5" - 2.6" H_2O). The entire process of diastole and systole occurs in about .833 seconds, with systole occuring for about .33 seconds on average.

14.1 Design of the Physiological Test Stand

With knowledge of these physical parameters, a mechanical system can be developed that responds in a similar way to the human cardiac cycle. The test stand must provide the proper filling pressures to the pig heart connected, and allow the left and right ventricles to pump into the correct dynamic pressures during the stroke volume. This volume must then be returned to the filling reservoir to maintain a closed cycle.

The systole process was accomplished quite easily by using a cylinder that each ventricle would pump into (see figure 14.1). Each cylinder was fitted with a piston, diaphragm, and adjustable spring. The fluid is pumped into the bottom of the cylinder through a port, which applies pressure to the piston and diaphragm. When this pressure reaches the opening pressure of the aortic or pulminary valve, depending on which side of the heart is being modelled, the force on the piston overcomes the spring force, causing the piston to lift off the seat. The fluid is forced out the side port, for which the flow is controlled by an adjustable valve. The valve is adjusted along with the spring force, so that the stroke volume may be exhausted into the cylinder, as the pressure increases from the initial opening pressure to the maximum pressure of either the aorta or pulminary artery, depending on which side of the heart is being modelled. While the heart is filling during diastole, the remaining fluid in the cylinder is allowed to flow through the adjustable valve so that the pressure in the cylinder returns to just below the opening pressure before the next systole cycle begins. This entire process is outlined in figure 14.2. The arterial pressure curves are not linear, and thus the linear response of the cylinder springs is not completely accurate, but for experimental testing this was justifiable.

Before each pressure cylinder could be fabricated, the required dimensions and spring force had to be calculated. The required motion, denoted with the variable names, is shown schematically in figure 14.3, for which Pi and Pf correspond to the initial and final pressures, respectively, A corresponds to the effective diaphragm area, k coprresponds to the spring constant, and di and df denote the initial and final piston positions. From step 2 in figure 14.3, we have

$$Pi \cdot A = di \cdot k$$

and from step 3 in figure 14.3, we have

$$Pf \cdot A = df \cdot k$$

also,

$$(df - di) \cdot A = V$$

The effective pressure area may be determined from

$$\text{Effective pressure area} = \left(\frac{\text{Cylinder Diameter - Piston Diameter}}{2} - \text{Cylinder Diameter}\right)^2 \cdot \frac{\pi}{4}$$

Pi, Pf, and V are given for each cylinder, and we are free to choose A, do, df, and k subject to:

$$\frac{di \cdot k}{A} = Pi \qquad (14.1)$$

$$\frac{df \cdot k}{A} = Pf \qquad (14.2)$$

$$A \cdot (df - di) = V \qquad (14.3)$$

The area, A, may be specified, and we then choose di, df, and k to satisfy

$$di \cdot k = Pi \cdot A \qquad (14.4)$$

$$df \cdot k = Pf \cdot A \qquad (14.5)$$

$$df - di = \frac{V}{A} \qquad (14.6)$$

using

$$(df - di) \cdot k = (Pf - Pi) \cdot A \qquad (14.7)$$

and

$$\frac{V}{A} \cdot k = (Pf - Pi) \cdot A \qquad (14.8)$$

results in:

$$k = (Pf - Pi) \cdot \frac{A^2}{V} \qquad (14.9)$$

$$di = \frac{Pi}{Pf - Pi} \cdot \frac{V}{A} \qquad (14.10)$$

$$df = \frac{Pf}{Pf - Pi} \cdot \frac{V}{A} \qquad (14.11)$$

An iteration of equations (14.9) through (14.11) with different areas for different springs chosen from a spring SPEC ® catalog (from Associated Spring Raymond) enabled the selection of a spring and area for each pressure cylinder.

The pressure cylinders were designed on a computer, and the specifications are given in Appendix V. With the pressure cylinders designed, the entire test stand was able to be designed (see figure 14.4). Ventricle inlet pressures were produced by small columns of water, corresponding to the diastole pressures discussed. These pressures were increased slightly to 15 mm Hg (8" H_2O) for both the right and left sides of the heart to account for the inability of the muscles of a dead heart to expand at low pressures.

14.2 Fabrication of the Physiological Test Stand

The entire structure of the test stand (shown schematically in figure 14.4), including all cylinders, was contructed from clear acrylic to allow visualization of the pumping process (see figure14.5 for completed test stand). The fabrication process entailed the contruction of all parts from stock acrylic cylinders and plates. Due to the

cylindrical properties of all parts, a lathe was used to machine all of the pieces except the diaphragm and the spring.

14.2.1 The Pressure Cylinders

The pressure cylinders (figure 14.1)were made from a 4 1/2" (114.3 mm) diameter cylinder of acrylic with a 1/4" (6.35 mm) wall thickness. The left cylinder was cut to 5.25" (133.4 mm), and the right cylinder was cut to 4.35" (110.5 mm) in length. Two 1/2" (12.7 mm) diameter holes were drilled in the side of the cylinders to fit an acrylic tube for the outlet ports. Two other holes were drilled at the top of each cylinder wall and tapped to fit 8-32 thumb screws. Six plugs were cut from 3/4" (19.1 mm) thick acrylic sheet, and turned to 3 1/2" (89 mm) in diameter to fit the ends of the cylinders. The two top plugs were drilled and tapped with a 1/2-13 thread to fit the spring adjustment screws, and drilled with 1/4" (6.35 mm) through holes to act as pressure relief ports. The two bottom plugs were bored with a 2.9" (73.6 mm) diameter flat that was 1/8" (3.2 mm) deep, and then drilled with a 1/2" (12.7 mm) diameter through hole to fit the acrylic tube that the flexible tubing would fit onto. The tygon tubing was in turn attached to the fittings on the heart. The last two plugs were bored with a 3.2" (81.3 mm) diameter hole that the diaphragm would attach to. The diaphragm was fabricated from the urethane dispersion used to produce the outer shell of the MBAD (see chapter 13) by dipping a glass beaker for which the bottom dimensions were exactly those required for the proper effective pressure area. Each diaphragm was dipped five times, following a similar dipping procedure as done to fabricate the MBAD, except that no release agent was required for the glass. Springs were obtained from Associated Spring- Raymond, Barnes Group with the proper spring constants. The pistons were machined from aluminum to fit the inner diameter of the springs, with the piston section 0.1" (2.54 mm) thick (they were machined thin to lower excess weight of the system, which could upset the correct pressures). The spring adjustment screws were made from polyethylene and nylon for the left and right cylinders, respectively, due to availability. The assembly of the cylinders was done in a way so that every part could be removed if required. The diaphragms were removed from the glass

beakers they were dipped on, and cut to the appropriate lengths. Different glues were tested for adhering the diaphragm to the inside wall of the bored plug- silicone, epoxy, acrylic, rubber cement, and liquid urethane; for which the urethane dispersion was the most effective. The piston was fitted into the diaphragm before the diaphragm was attached to the plug, because the piston base is larger than the hole in the plug. The plug was attached to the interior wall of each main cylinder with silicone adhesive, at the height at which the diaphragm base rested on the bottom plug. The bottom plug was also attached to the inner cylinder wall with silicone. Inside each diaphragm, a 3" (76.2 mm) diameter acrylic cylinder with a 1/4" (6.35 mm) wall thickness was turned to slide in each bored plug, to keep the piston from 'cocking' while moving upward, and to keep the fluid from pushing the diaphragm sides inward. The top plug fitted with the spring adjustment screw and spring, was attached to each cylinder by tightening the thumb screw attached to each main cylinder wall. At this point, both cylinders were ready to be calibrated.

14.2.2 Calibration of the Pressure Cylinders

Calibration of each pressure cylinder was done separately, using a column of water to provide the correct pressures to the diaphragm. The spring adjustment screw was turned to either increase (clockwise) or decrease (counter-clockwise) the force applied to the piston. A peristaltic pump was used to fill a column with water, which was marked with the required water levels.

The right pressure cylinder was calibrated by filling the column with 4.3" of water (8 mm Hg), at which pressure the diaphragm was supposed to lift off the seat. The adjustment screw was adjusted until this occured. The column was then filled to 13.4" of water (25 mm Hg), at which point the piston was supposed to be off the seat by .44 inches (11.2 mm), corresponding to the 70 ml (2.4 ozfl.) volume that was to be pumped. The screw was adjusted slightly and the process was repeated until the piston responded to within a 1/2" of water (1 mm Hg) accuracy.

The left cylinder was calibrated in a similar manner, except the water column heights were significantly higher. The column was filled to 43" of water (80 mm Hg) for

the piston to lift off the seat, and 64" of water (120 mm Hg) for the piston to be .44" (11.2 mm) off the seat. This cylinder was only accurate to within about 2" of water (4 mm Hg).

14.2.3 Completion of the Test Stand

The inlet pressure water cylinders were cut from a 1/8" (3.2 mm) thick, 1 1/4" (31.8 mm) diameter acrylic cylinder. The length of the left inlet cylinders was 8" (20.3 cm) and the right cylinders 8.9" (22.6 cm). The right cylinders were longer to enable the bottom of the two arterial pressure cylinders to be at equivalent heights when attached with the inlet cylinders. A 1/2" (12.7 mm) diameter hole was drilled through both walls of each cylinder, 1" (25.4 mm) from the bottom, and an acrylic tube was inserted through the two cylinders, which were separated by 1/2" (12.7 mm), so they protruded by 1/2" (12.7 mm) on either side of the cylinders. The inserted acrylic tube was perforated with 1/8" (3.2 mm) diameter holes in the sections that were surrounded by the cylinders, thereby allowing water to pass from one cylinder to another.

Two inlet cylinders were attached to the top plug of each pressure cylinder so that the screw fit between the two cylinders. The cylinders were attached permanently with acrylic glue, and thus formed a waterproof seal at the bottom of each cylinder. The other end of the cylinders were then attached to the top interior of a box that had been fabricated from 1/2" (12.7 mm) acrylic sheet. The box dimensions were approximately 12" (30.5 cm) wide by 21" (53.3 cm) high by 12" (30.5 cm) deep. A 1" (25.4 mm) hole on the top of the box, directly above a cylinder on each side, enabled the cylinders to be filled.

The two side ports, as well as the bottom ports on the pressure cylinders, were fitted with a 1" (25.4 mm) long piece of acrylic tube, enabling flexible tubing to be attached. On the flexible tubing between the inlet cylinder and the outlet port of the pressure cylinder, for both pressure cylinders, an adjustable screw-operated tubing clamp was placed to act as a flow control valve.

The ports on the inlet cylinders, as well as the inlet ports on the pressure cylinders, were attached with flexible tygon tubing, which would attach to the fittings on the pig

heart. Inside each of these tubes, a check valve was placed to allow flow in only one direction. In the venus pressure outflows, the valves were placed to allow only flow out of the inlet cylinders. For the inlets of the pressure cylinders, the valves were placed to allow only flow into the cylinders. These valves enabled the pig valves to be removed, which were generally damaged anyway, and took place of their function in preventing unwanted flow direction.

With all of the parts in place and functioning correctly, the test stand was ready to test the pig hearts for pumping efficiency, and the MBADs for functionability.

15.0 Development of a Refined MBAD

A new mold was developed to improve the fabrication process of new MBADs and overcome the problems of retention (see chapter 13). With the completion of a new physiological test stand, more testing of the original MBAD was conducted, including retention methods, bladder orientations, and sizing. The information gained from this testing was used to design and fabricate more urethane MBADs. The production of more MBADs by dipping required several alterations to the dipping machine. All of this will discussed in the following paragraphs, up to and including present testing and fabrication (see published date) of the MBAD.

15.1 Fabrication of a New Heart Mold Replica

A new mold (shown in figure 15.1) that would enable the easy removal of the urethane bladders without the application of gelatin (see chapter 11), and that would allow the MBAD to extend higher on the heart (see chapter 13) was developed and fabricated. The plaster male replica was cast from the original silicone female mold that was used to cast the previous two plaster heart molds (see the end of chapter 6 for details in the process). After the plaster mold was removed from the silicone female mold, more plaster was mixed in the appropriate concentration, and added to the top of the mold in order to fill in the indentations caused by the aortic arch. More plaster than required was added, forming a mound on the top of the mold. This was desired so that the excess plaster could

be removed after it had dried, in order to form the rounded top conceived during the testing of the pig hearts (see chapter 13). Plaster was also added to some of the imperfections on the mold caused by air bubbles. The mold was then allowed to dry overnight.

A large glass cylinder about 1 1/2' (.46 m) in diameter and 1 1/2' (.46 m) long was turned on its side and braced to keep it from rolling. A plastic sheet was placed over the open end with two 4" (100 mm) long slits in the plastic that would enable one to insert both hands to work within the glass cylinder. The plaster heart mold was placed in the cylinder, and using a Dremel™ motor tool attached with a grinding wheel, the excess plaster was sanded from the mold. The glass cylinder was used to retain the powder produced from this operation, while enabling observation of the process. The mold was sanded so that it extended higher than before by about 2" (50.8 mm), with a rounded top.

Plaster was again mixed in the appropriate concentrations and thinly applied to any grooves or imperfections in the plaster mold. Water was rubbed over the applied plaster by hand in order to smooth the application of the plaster as well as eliminate any discontinuities. The plaster was allowed to dry for several hours, after which the process was repeated. The procedure was undertaken a total of three times, after which the mold was allowed to dry overnight. The following day, the mold was carefully held in a drill press and the top drilled very slowly with a clearance hole to fit a 1/4" - 20 threaded rod, which was held in place with epoxy. The mold was finely sanded with emory paper (240 grit), and wiped free of particles with a damp sponge. The mold was now ready to be coated with a release agent.

Several different materials were tested as release agents for the polyurethane material. They were tested on a small piece of plaster. The different materials tested were teflon, glass, polyethylene (low and high densities), epoxy (polyester), and silicone elastomers. Teflon dust applied via a spray can did not coat the plaster well enough to release, and to melt a sheet of teflon to conform to the mold would be too difficult. Glass worked excellently as a release for the urethane, though it is quite difficult to form into the appropriate shape (a glass blower was considered to do this task, but it was decided there were easier means by using a different material). Polyethylene also worked excellently as a

release, but is difficult to apply to the mold. Liquid polyethylenes that could be dipped or sprayed were searched for, but could not be found. The companies that were contacted were Mobil Chemicals Inc., Dow Chemicals, Eastman Chemicals, and Allied Chemical. An epoxy paste and epoxy liquid for repairing boats were tested for release of the urethane and both were shown not to work very well. The boat epoxy did not enable the release of the urethane, and the epoxy paste left a residue upon the urethane that was difficult to remove. Silicone elastomers worked excellently as a release, and could easily be applied by dipping or spraying onto the plaster mold. The problem with the silicone is that it does not stick to the plaster. The way to avoid this problem is to apply a rigid enough coating all around the mold so that the coating cannot stretch to pull from the mold or slip off because it extends all around the mold. Due to the ease of application of the silicone elastomer, it was decided to be the best material for a release agent. The material, Silastic® Q7-2213, was obtained from Dow Corning Corporation (the material specifications are given in appendix II).

The silicone elastomer (Silastic® Q7-2213) is a heat curable dispersion that may be brushed, dipped or sprayed. The viscosity may be adjusted with the addition of 1,1,1 Trichloroethane. The dispersion (as obtained from Dow Corning) will cure in 15 minutes at 320℉ (160℃). Due to the unavailability of an oven at the time, a heating coil was used to test the curing of the silicon. The coil consisted of a 25' (7.6 m) long resistive wire wrapped around a 6" (152.4 mm) diameter wire cylinder that was about 8" (203 mm) long. The temperature inside the cylinder was controlled at 105℉ (40.5 ℃), and the mold, coated with a layer of the silicone by dipping it into a beaker of the dispersion, was kept at this temperature for more than 4 1/2 hours, after which it was still tacky. The silicone was carefully stripped from the mold (it did not stick to the plaster) and it was decided that an oven was required to cure the silicone.

The heart mold was dipped into the silicone, as before, and put in an oven (a small oven in the Chemical Engineering Dept.- Bldg A, rm C312) at 320℉ (160℃). The coating, upon being heated, began to bubble excessively, as if the solvents were boiling, and with the small thickness of the coating, caused the coating to deform. The coating was removed

after 20 minutes, and the silicone had cured into a very tough elastomer, although the coating was filled with holes and craters due to the bubbling effect. In hopes of eliminating this phenomenon, the dispersion was thinned by 50% with the addition of 1,1,1 Trichloroethane. The silicone coating on the plaster mold was removed, and the process was duplicated with the thinned silicone dispersion. Again, the bubbling effect occured, but not quite as extensively.

To avoid this bubbling effect, it was decided to coat the mold with silicone, and let it cure partially at an elevated room temperature for an extended period of time, after which the mold would be completely cured in the oven. This partial curing time would enable most of the solvent to evaporate slowly without boiling. Over a five day period, the plaster mold was dipped 33 times into the silicone dispersion (which was thinned to 25% of its original concentration of 13% solids), after which the mold was allowed to partially cure (more than it had cured at room temperature between dips) at 90℉ (32.2 ℃) for three days. The coating was then heated in the oven for 25 minutes at 230℉ (110℃), and let cool overnight.

The silicone coating (shown on the mold in figure 15.1) turned out to be very smooth, and rigid enough not to pull from the plaster mold. In order to fully test the mold, the mold was dipped into the polyurethane dispersion three times with 1/2 hour drying times between dippings. The entire mold was dipped so that urethane would extend over the entire top of the heart, except in the position of the threaded rod that holds the mold in the dipping machine. The coating was allowed to dry overnight, after which the coating was removed. The removal process involved inserting a hypodermic needle between the outer surface of the silicone and the inner surface of the urethane shell, and inflating this region with compressed air. This lifted the urethane shell from the silicone to ease the removal. A slit was made in the top of the shell, and the urethane was stretched until the mold could could be removed. This action slightly plastically deformed the top of the urethane shell where it had been stretched significantly.

15.2 Continued MBAD Testing

In order to fully understand the pumping effects, to decide on proper bladder orientations and retention methods, extensive testing of the MBAD on actual pig hearts was required. The completed test stand was used to monitor the pumping action and provide the proper pressures for the heart to pump against. On four different occasions, hearts were obtained, prepared, and tested. It should be mentioned at this point that the hearts were requested with the extension of both arteries and veins as long as possible, otherwise the butcher would not be careful during the slaughtering process, andwould sever these tubes too close to attach the fittings. Also, for testing purposes, the hearts were requested to be as small as possible, thus allowing them to expand into the MBAD (this will be discussed further in the details that follow). The four different testing occasions will be combined and the information that was gained will be discussed.

The hearts were prepared in a similar manner to that discussed in chapter 13, using aluminum fittings for all inlet and outlet connections except that all of the valves were removed internally from the heart because valves were placed externally in the test stand. All tubes that were required to be closed were secured with kevlar® thread by tying the thread tightly around the tube with a knot. The fittings were connected to the appropriate pressure and inlet cylinders of the test stand (chapter 14), and before water was allowed to fill the ventricles, the MBAD was placed around the heart so that the heart would not over expand (the right side of the heart as well as both atria would expand considerably under pressure, for the retaining muscle has died). The inlet pressures may then be opened, allowing the ventricles to fill with water. The MBAD pumping unit (chapter 12) was then used to pump water through the heart by the pressure cycling of the MBAD.

The testing gave a better understanding of the required retention methods, for without retaining the MBAD in any way, the pumping pushed the MBAD off the heart. A strap around the the top of the heart (under the aortic arch) underwent tremendous tension due to the forces causing the MBAD to push off, so a vacuum was introduced to the apex of the MBAD in order to maintain the apex of the heart in the MBAD. The vacuum source used was a small 12 volt air compressor rated at 250 p.s.i. (1.72 MPa) pressure. The inlet

port of the compressor was connected with a fitting, to act as a vacuum port. The MBAD was altered by adding a tube to the apex in the same method that the tube was attached to the bladder connection (see chapter 11). The use of a vacuum source to retain the heart in the MBAD worked extraordinarily well, except that the position of the bladders on the MBAD tended to push the sides of the MBAD off the heart in a wrinkling fashion (see figure 15.2). To eliminate this effect, it was decided to add stiffeners to the MBAD so that it can not wrinkle. The most desireable technique is to add stiffeners that are made from a compatible urethane (with a higher stiffness) so that the MBAD continues to be a one part design (for the tubing can be a part of the design by using more advanced manufacturing techniques). An alternative to adding stiffeners is the masking of stiffening bladders during the fabrication process. These bladders will not assist in pumping, but will merely fill with air, preventing wrinkling from occuring by remaining stiff under pressure.

The optimum positioning of the bladders was determined by placing a urethane shell around the pig heart and pumping the heart by hand until the optimal flow rates at the appropriate pressures were obtained (the shell was produced when testing urethanes for the best bladder material- chapter 11). The shell was marked at the contact points where the fingers were positioned, and the bladder was drawn onto the shell with a permanent marker (see figure 15.3) so that it formed areas equal and opposite in both the horizontal and vertical planes. This would prevent the forces on the heart from causing the MBAD to be pushed from the heart. The dimensions of the bladders were determined as the largest areas that could be placed on the surface without affecting the structure of the MBAD, or without pushing excessively on the sides of the ventricles, because a normal force would produce the maximum pumping action. By having the areas as large as possible with these effects considered, the volumetric flow rate could be adjusted for each pump, to control the amount of flow produced, along with the pressure, to control the desired force applied to the heart.

Two of the problems experienced during the testing process were the excess expansion of the atrium, and the inability to fill the heart properly. This inability to fill the heart stemmed from the problem that the hearts obtained were too large for the MBAD, so

the ventricles would not expand to fill the MBAD. The MBAD would keep them from expanding, and thus filling with the appropriate volumes. To solve this problem, a larger MBAD could be produced, or smaller pig hearts could be obtained. The latter choice was made, and the butcher was requested to provide smaller hearts to us. This was done, thus solving the problem.

Excess expansion of the atrium was caused by the inability of the muscle and tissue to resist stretching, as mentioned in regard to the right ventricle upon filling. This stretching was caused by excess pressure due to the fact that the valves had been removed internally from the heart, and thus the atrium would feel the pumping pressure during the systole pumping cycle. This expansion of the atrium did not enable pumping to be accomplished, so two different methods of retaining the atrium were tried. It should be noted at this time that the atrium were not required to function in any way for the hearts being tested. The first method of retaining the atrium involved a velcro strap that could be adjusted to hold the atrium from expanding, but this did not seem to work because the whole top section of the heart expanded, carrying the velcro retainer along with it. The second method involved tying the top section of the heart. This required extending the aluminum fittings into each ventricle so that the flow would not be blocked upon tying the top section of the heart tight. This was accomplished by inserting flexible PVC (polyvinyl chloride) tubing into the interior of the fittings to the desired length (see figure 15.4). The top section was tied off using wire. Each atrium was then tied off using kevlar® thread by tying a knot under each atrium where it connected to the heart. This technique worked sufficiently in abating the expansion of the upper half of the heart.

15.3 Alterations to the Dipping Machine

In order to produce an MBAD from the urethane dispersions, the mold was dipped as discussed in chapter 11. The urethane dispersions could not have a layer of water over them during dipping due to their lower densities, and it was undesirable to use another liquid due to the affects caused on the wetting ability of the urethane. In order to keep the urethane from hardening in the container, a lid had to be placed on the container. Thus,

before every dip (with a repeat rate of 1/2 hour), the container's lid had to be removed, and then replaced after the dip. This inconvenience did not make the automatic dipping machine very 'automatic', so an alteration was made to the machine to automatically remove a lid to the dipping dispersion before each dip, and replace it following the dip. This alteration will be discussed in the following paragraphs.

The dipping machine (as discussed in chapter 8) utilizes pneumatics in order to actuate the dipping motion, and thus the actuation of an automatic lid for the coating dispersion container was designed to function pneumatically in a similar way. Due to space limitations, the motion of the movable lid was restrained to an on and off sliding motion along the top rim of the container. With the heart mold positioned a little over an inch (25.4 mm) above the top of the container, any hinged or pivoting movement deviating from the plane of the container's top could interfere with the mold. The optimal motion therefore was a linear sliding motion of the top, actuated by a pneumatic cylinder (see figure 15.5). Two double-acting cylinders with 4" (102 mm) long strokes were used to accomplish this motion. The cylinders were attached to the back of the dipping machine in such a manner that the piston shafts traveled parallel to each other and to the top of the container. The ends of the shafts were connected to a 1/16" (1.6 mm) sheet of acrylic coated on the bottom side with a sheet of teflon film to provide minimal friction with the container's rim. A slot was cut in the back of the dipping machine to allow the movement of the acrylic cover past the back of the machine when the cylinders closed.

A 4" (102 mm) stroke length was determined to be long enough when the heart was positioned so that the smallest thickness passed between the lid and the side of the container. This required that the heart did not rotate at all during dipping. To ensure that the heart did not rotate, a support rod was added to the dipping piston (see figure 15.6). The support rod was attached to the end of the piston shaft by means of a hex screw, and positioned so that it would travel through a hole in the support for the dipping cylinder. The result was equivalent to a double shafted cylinder with only one shaft actuated pneumatically. This fixture thus prevented the rotation of the dipping cylinder.

Another anticipated difficulty was the possibility of the dispersion container

moving from the frictional forces applied by the moving lid onto the rim of the container. In order to prevent this from occuring, a crome- plated steel disk was attached to the bottom of the dispersion container (which was made from a non-ferritic stainless steel) with epoxy, and a holding magnet (18 lb (80 N) holding force) was attached flush with the floor of the dipping machine. The magnetically attracted steel disk on the bottom of the container adhered strongly to the holding magnet, not permitting very easy movement of the container (this created some difficulty with removing the container in general, but worked excellently for strong holding during the lid's movement).

The final concern of this addition to the dipping machine was the control of the automatic lid, so that it would not collide with the heart mold, yet functionally open and close before and after the dipping operation, respectively. This control was accomplished by installing both a pressure regulator and a flow control valve onto the pneumatic system for the dual piston arrangement (see figure 15.7 for modified pneumatics). The lines were connected so that during drying of the heart mold coating (up) the gas pressure went through a needle valve into the back ports of the lid cylinders. This would cause the cylinders to open slowly, forcing the lid closed. A self- relieving pressure regulator was connected between the supply from the original pressure regulator, and the front ports on the lid cylinders. This could be adjusted so that the closing speed of the cylinders (opening speed of the lid) could be adjusted as the three-way solenoid valve is activated, which causes the pressure in the dipping cylinder and the back of both lid cylinders to drop to atmospheric pressure, and for the mold to dip. It is imperative that this be a self- relieving type regulator, for the gas pressure must be released from this regulator when the cylinders open to close the lid.

The automatic lid described functioned very well, enabling the dipping machine to function automatically and produce additional MBADs that continually improve in functionability.

15.4 Fabrication of a New MBAD

Another MBAD was formed (see figure 15.8) by dipping the new mold into a

urethane dispersion with the improved dipping machine. The process was conducted in a similar manner to the previous MBAD, except that a release was not required on the mold in order to remove the MBAD. Using the urethane shell previously marked for bladder shape, size and orientation, gelatin was applied to the bladder using a small paint brush. The small paint brush was used to paint the outline of the bladders, after which they were filled in with gelatin using a foam brush. A ribbed section was attempted by forming verticle lines of gelatin between the bladders, which would fill with gas upon actuation. This was done to eliminate the wrinkling effect discussed earlier. The bladders were connected by a top and bottom ring that ran circumferentially around the heart. Between the rings, three ribs were 'painted' on each side of the mold. The tubing connections were formed at the apex of the heart- one for vacuum, and the other for cyclic pressure and vacuum to the bladders attached at the bottom ring.

16.0 Conclusion

A mechanical biventricular assist device was successfully developed, and shown to be capable of externally pumping the heart using pressurized bladders. Many tests must still be conducted before actual medical use may be implemented. With respect to several of these tests, and additional related concepts, future considerations will be discussed in the following paragraphs.

16.1 Future Considerations

Future considerations that have been conceived during the development and manufacturing process include comments on clinical testing, low friction coatings, catheter removal, optimization methods, endurance testing, quality control techniques, and production methods. All of these considerations will be described in the following paragraphs.

16.1.1 Clinical Testing

With the development of MBADs that function flawlessly under laboratory

conditions (realized compression of both ventricles under the correct pressures, retention on the heart, and endurance testing without failure), the clinical testing procedures may be undertaken. Before any testing may be conducted, a method for actuating the MBAD on the correct timing cycles must be developed. A modification to the intra-aortic balloon pump machine or the connection of several machines in parallel were discussed as possibilities.

16.1.2 Low Friction Coatings

A method of reducing the shear effects on the exterior of the heart, produced by frictional rubbing by the bladders of the MBAD, must be determined. Several different methods are discussed in chapter 2. The last method listed was the use of low friction coatings that could be applied to the interior of the MBAD. A very low friction coating that is available for medical usage (used on pacemaker lead wires) is a hydromer® (produced by Hydromer Inc.). In order to exhibit low frictional properties, the coating must first absorb water. The coating will adhere very well to urethane, although it will require oven curing, which may present a problem because of the low melting temperature of the urethane material.

16.1.3 Catheter Removal

The concept of implanting the MBAD after a heart operation in order to assist the weakened heart is strengthened by the thought of being able to close-up the patient, and remove the MBAD at a later time through a catheter. The details of this concept have not been determined, though fabrication of MBADs that are collapsible has been successfully accomplished. By fabricating the MBAD in such a manner that it will fold like an umbrella, as well as be retained on the heart by means of a vacuum, the MBAD may be removed through this technique.

16.1.4 Optimization Methods

Optimization of the bladder orientations, shapes and sizes must be accomplished.

This may have to be a trial and error process in the laboratory, conducted by fabricating many MBADs and testing for pumping efficiency on a particular heart or set of hearts. Computer simulations may assist the optimization process, but this should still be confirmed by laboratory tests.

16.1.5 Photoelastic Evaluation Techniques

Endurance and quality control may both be accomplished through the use of photoelastic evaluation techniques [18]. The MBAD urethane material responds quite well optically to inherent and induced stresses. In order to accomplish fatigue and endurance testing of the MBAD, it may be cyclically pumped for different lifespans on the heart, after which it may be examined using photoelastic measurement techniques, and any plastic deformations will be seen clearly. Following testing for leaks by blowing air through the bladders while submerged under water, quality tests may be further executed by viewing the completed MBAD using photoelastic measurement techniques. Any inherent stresses will be seen clearly, indicating possible bubbling of the dispersion during dipping, the presence of dirt particles, etc.

16.1.6 Production Methods

The three parts of the entire MBAD production process- fabricating the mold, forming the bladders, and attaching the tubing, all can be advanced considerably when production of many units is considered. In terms of fabricating a mold, two different concepts must be considered. Several different mold sizes may be produced in order to fit different size hearts. This would require the fabrication of several different sized molds. Alternatively, a custom MBAD could be formed for the individual by using magnetic resonance imaging (MRI) or similar techniques to digitize the dimensions of the heart into a computer which would send the information to a machine to fabricate the mold. Different machines to fabricate the mold from different polymers, wax, gelatin, plaster , or silicon are currently available (ie. CNC milling, stereolithography).

The forming of bladders must be accomplished in a repeatable manner. The

simplest method of accomplishing this task is to utilize a mask that can be fabricated by chemical machining or cut by an alternative method. The mask may be placed over the bladder (which is cured on the mold), and the gelatin layer may be either brushed or sprayed onto the unmasked areas.

The tubing may be fabricated as part of the MBAD when the mold is being dipped, because the tubing may connect to the apex of the MBAD. In order for the tubing to be produced by this method, the mold must be attached at the apex with rods of material to which the urethane does not permanently adhere, of the desired tubing length, and dipped to coat the entire assembly.

Figures

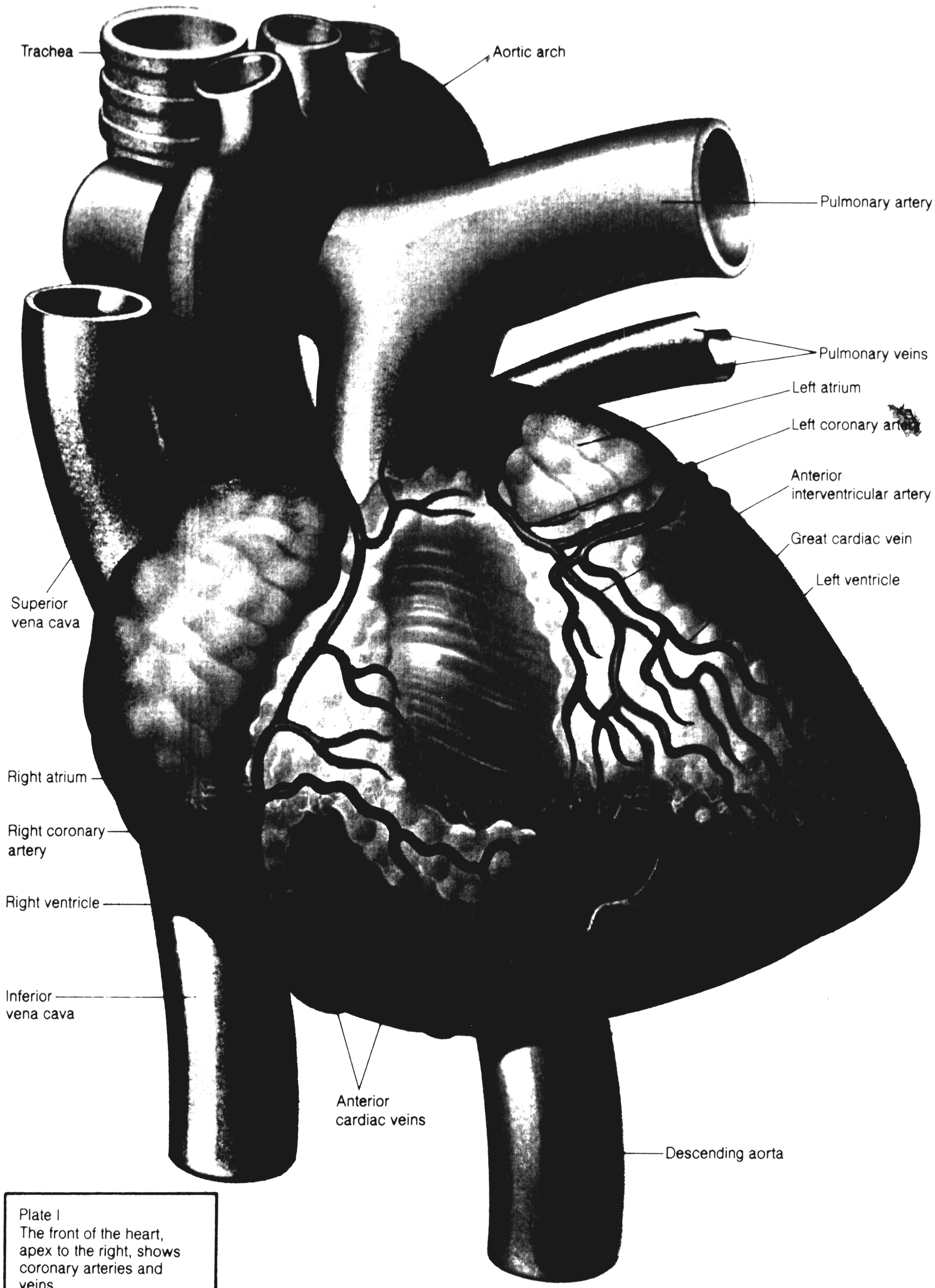

Plate I
The front of the heart, apex to the right, shows coronary arteries and veins.

Figure 2.1: Heart Structure, Ref 15

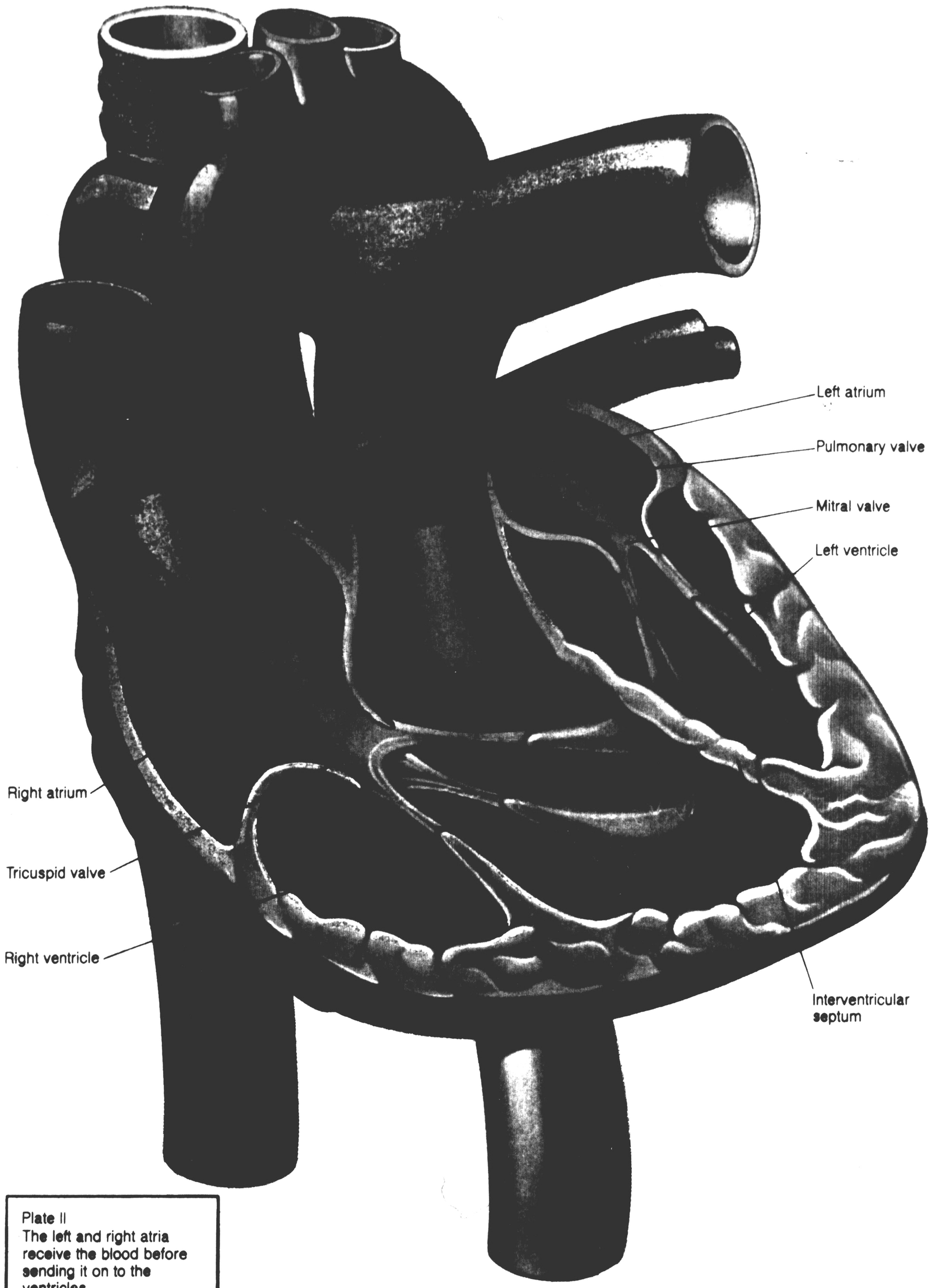

Plate II
The left and right atria receive the blood before sending it on to the ventricles.

Figure 2.2: Heart Structure and Path of Blood, Ref 15

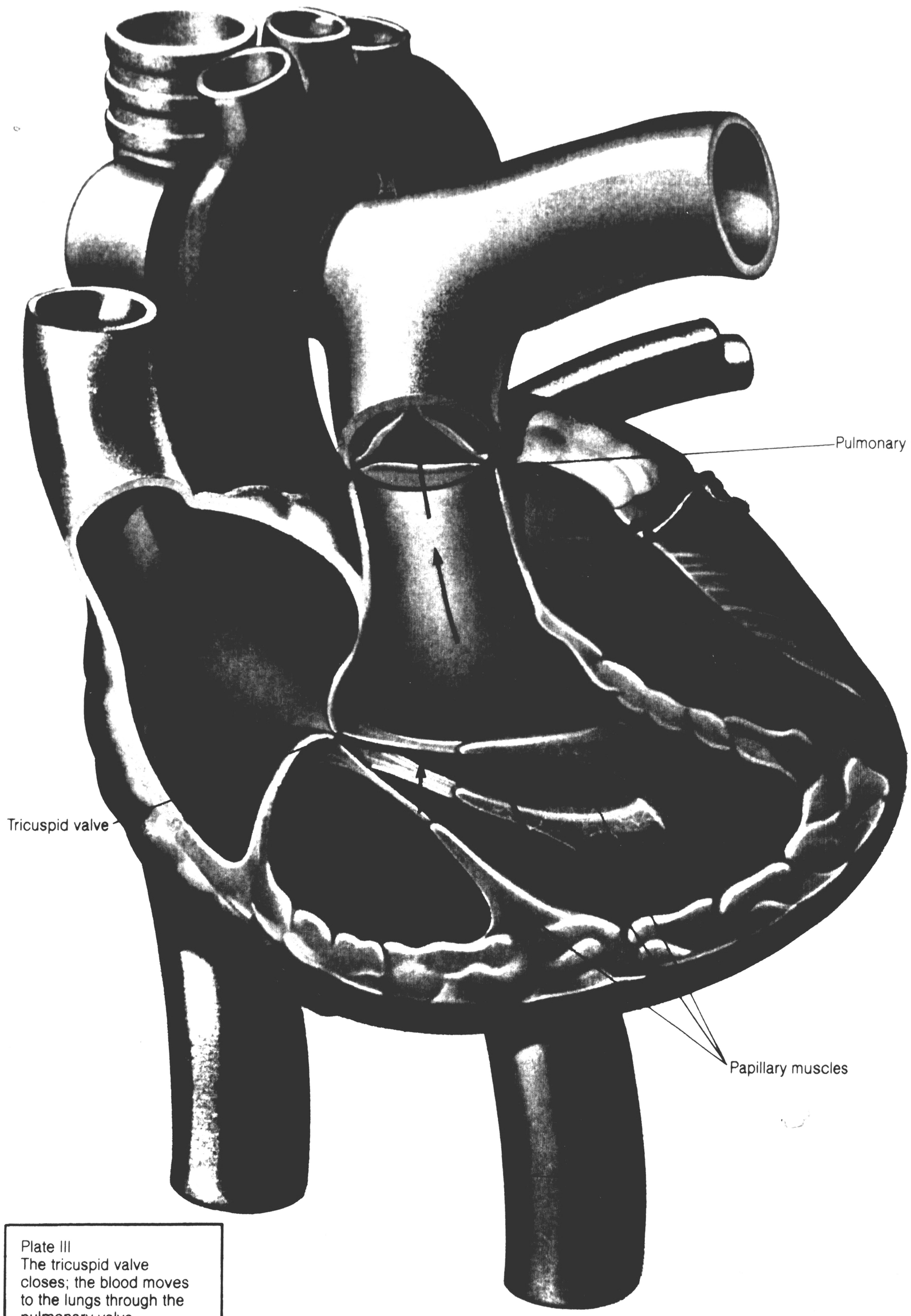

Plate III
The tricuspid valve closes; the blood moves to the lungs through the pulmonary valve.

Figure 2.3: Heart Structure and Path of Blood (Continued), Ref 15

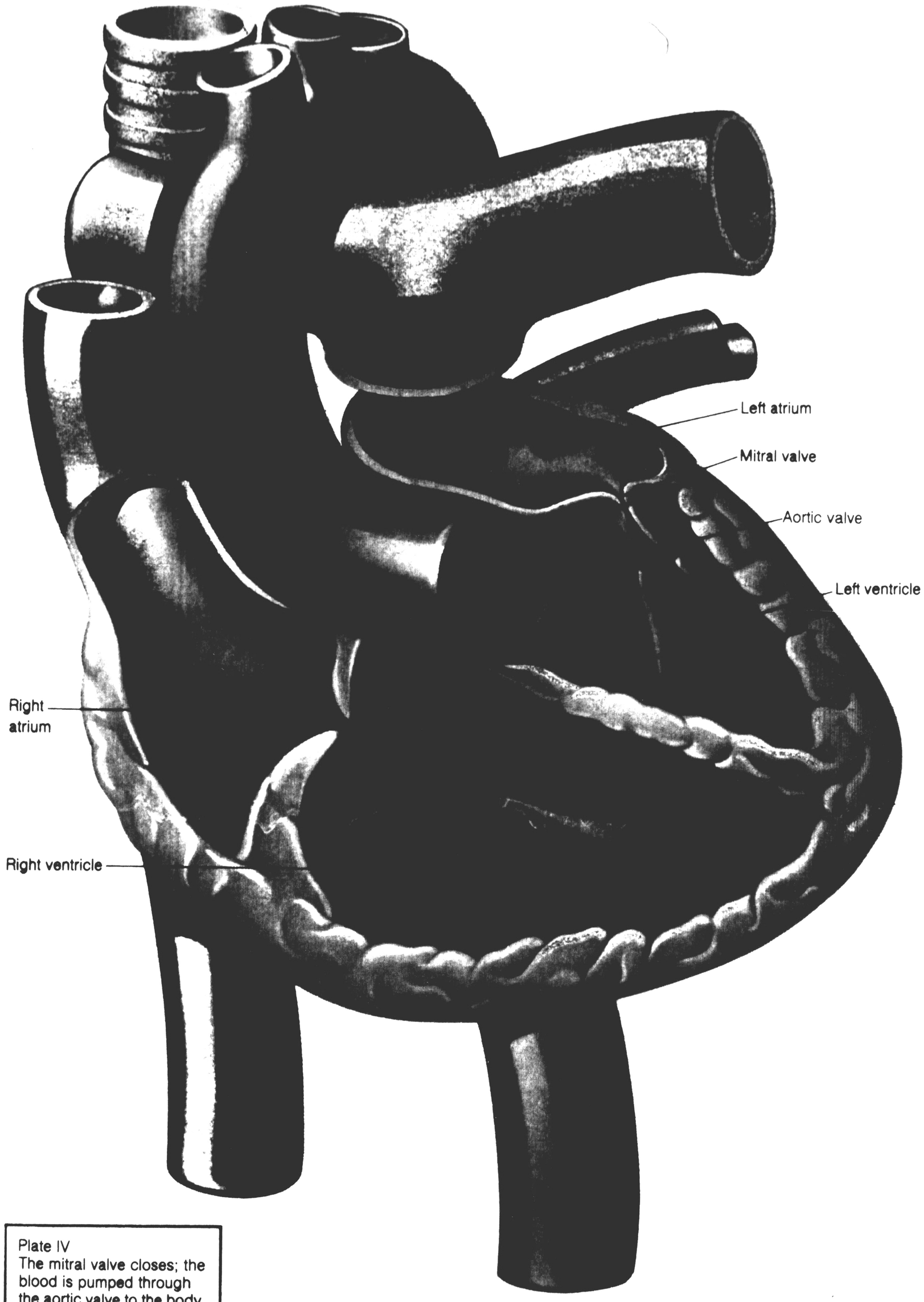

Plate IV
The mitral valve closes; the blood is pumped through the aortic valve to the body.

Figure 2.4: Heart Structure and Path of Blood (Continued), Ref 15

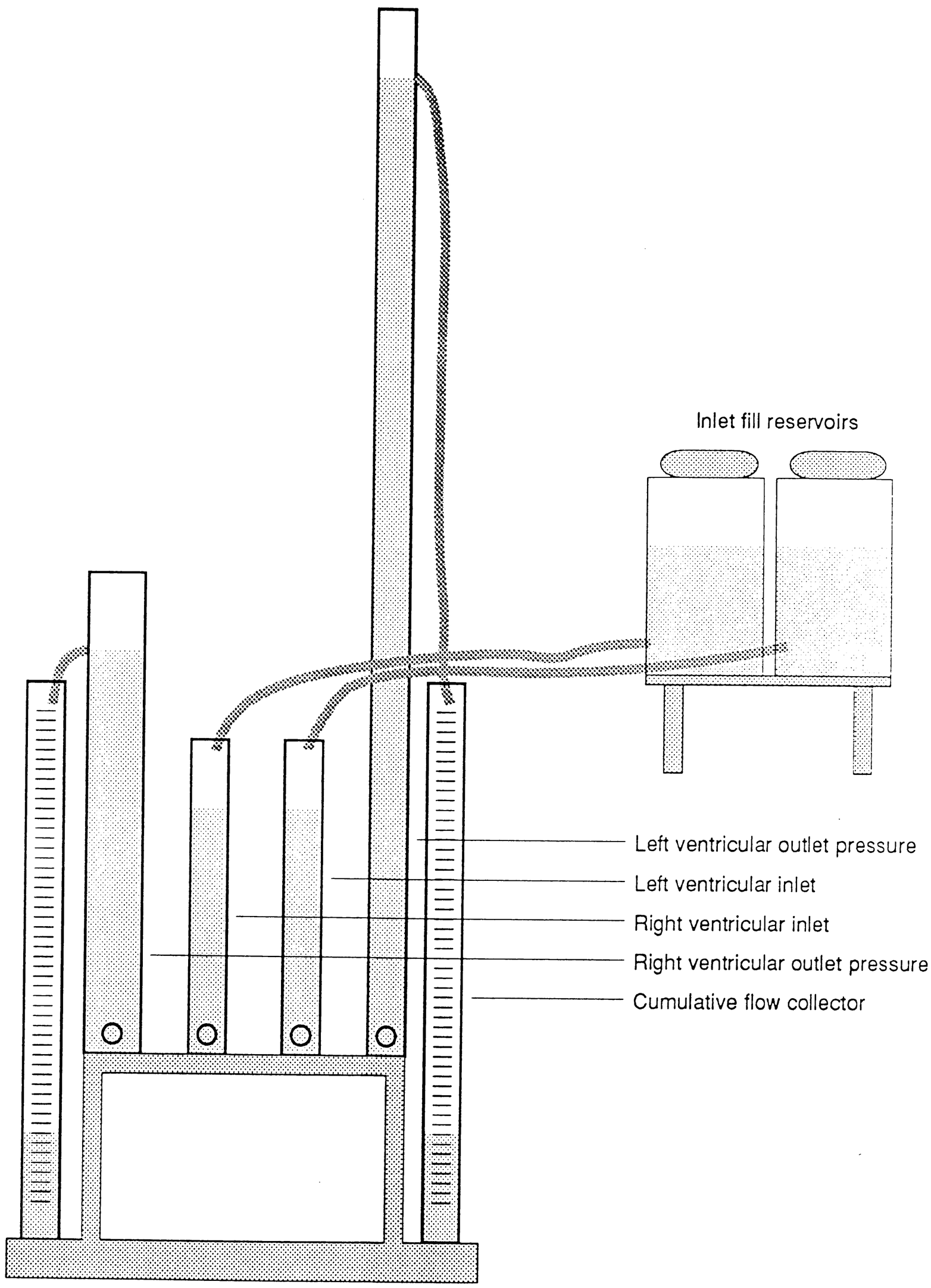

Figure 2.5: Test Stand

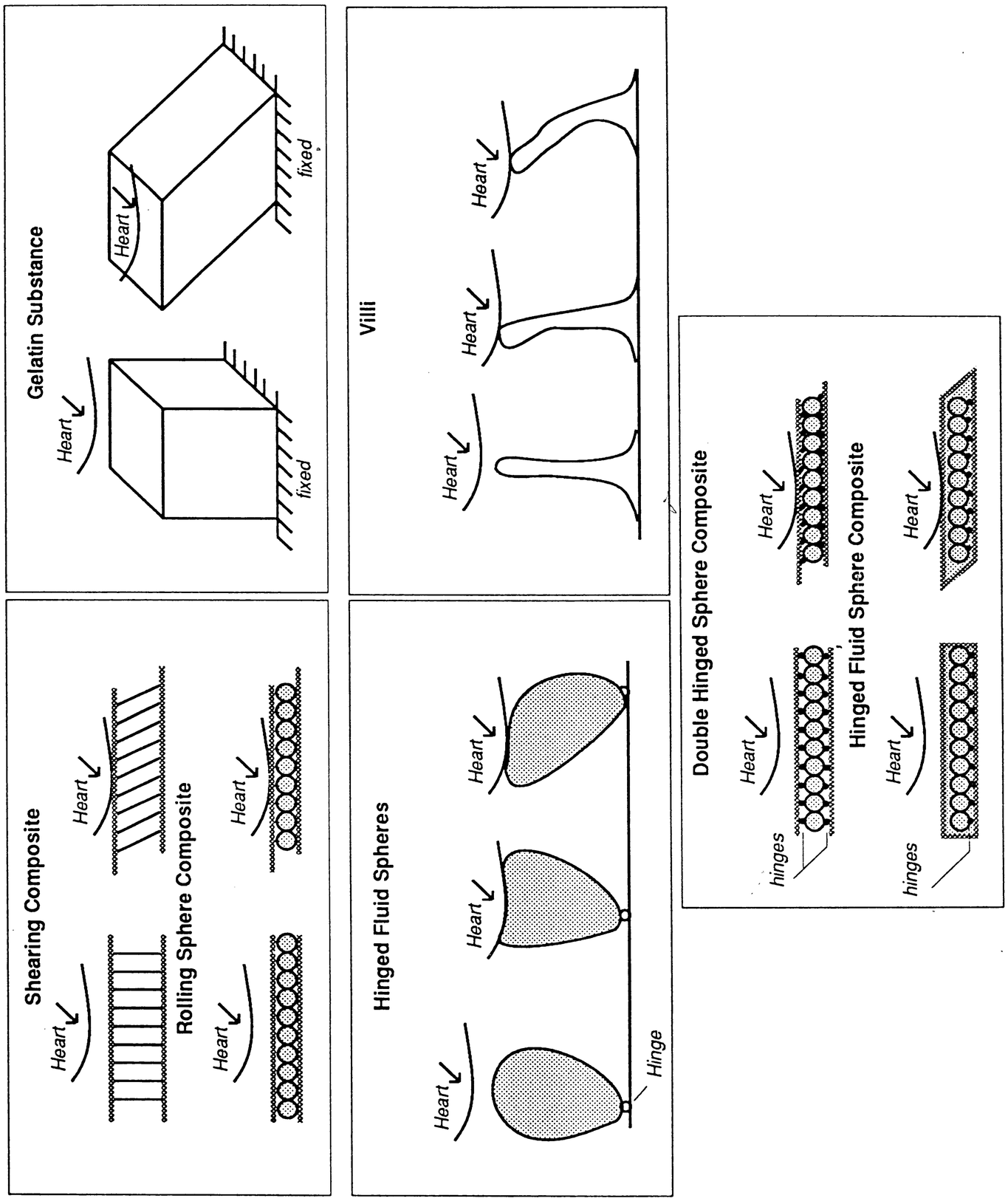

Figure 2.6: Shear Layers

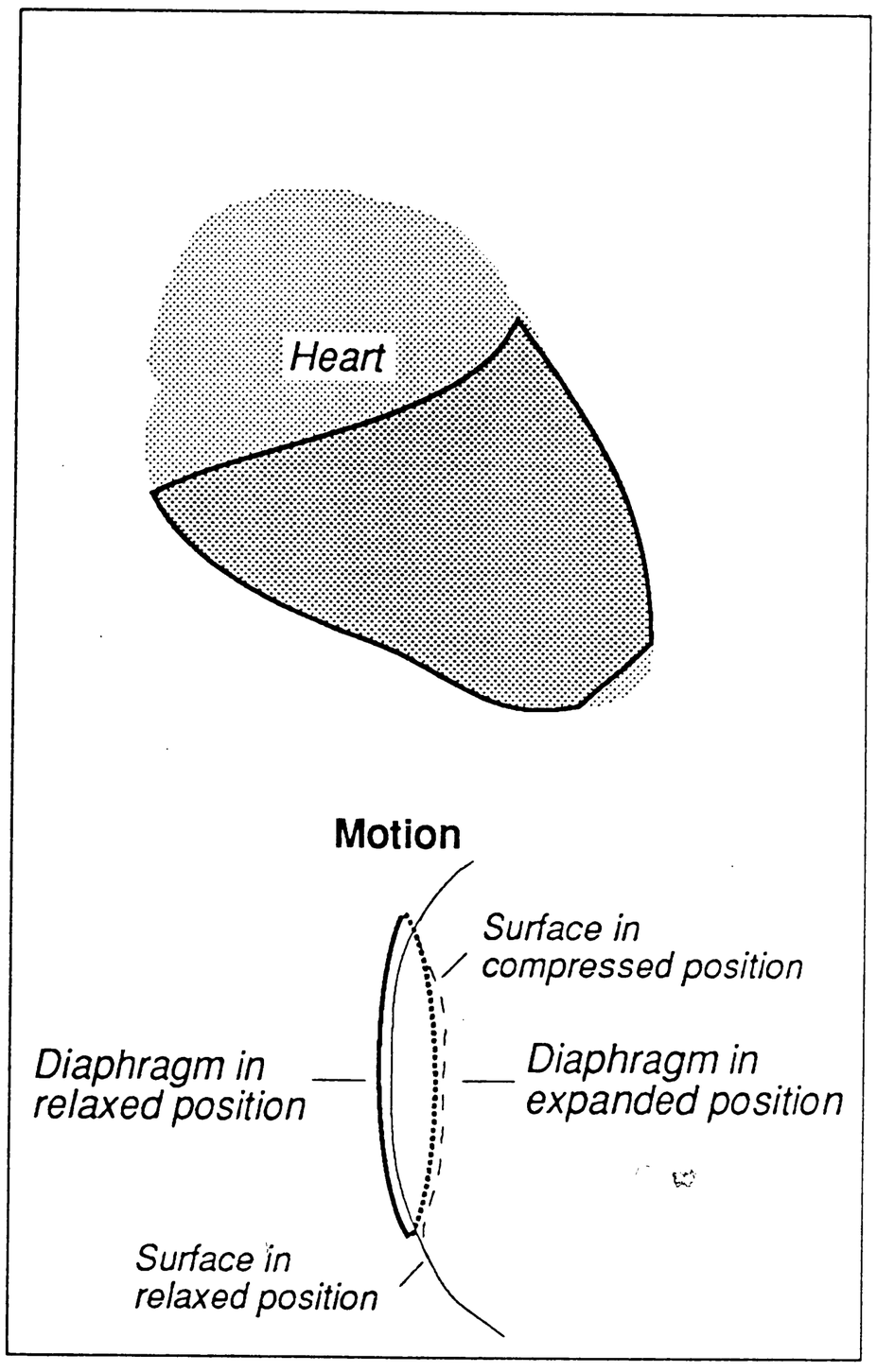

Figure 3.1: Pneumatic Actuation Techniques: Bladder

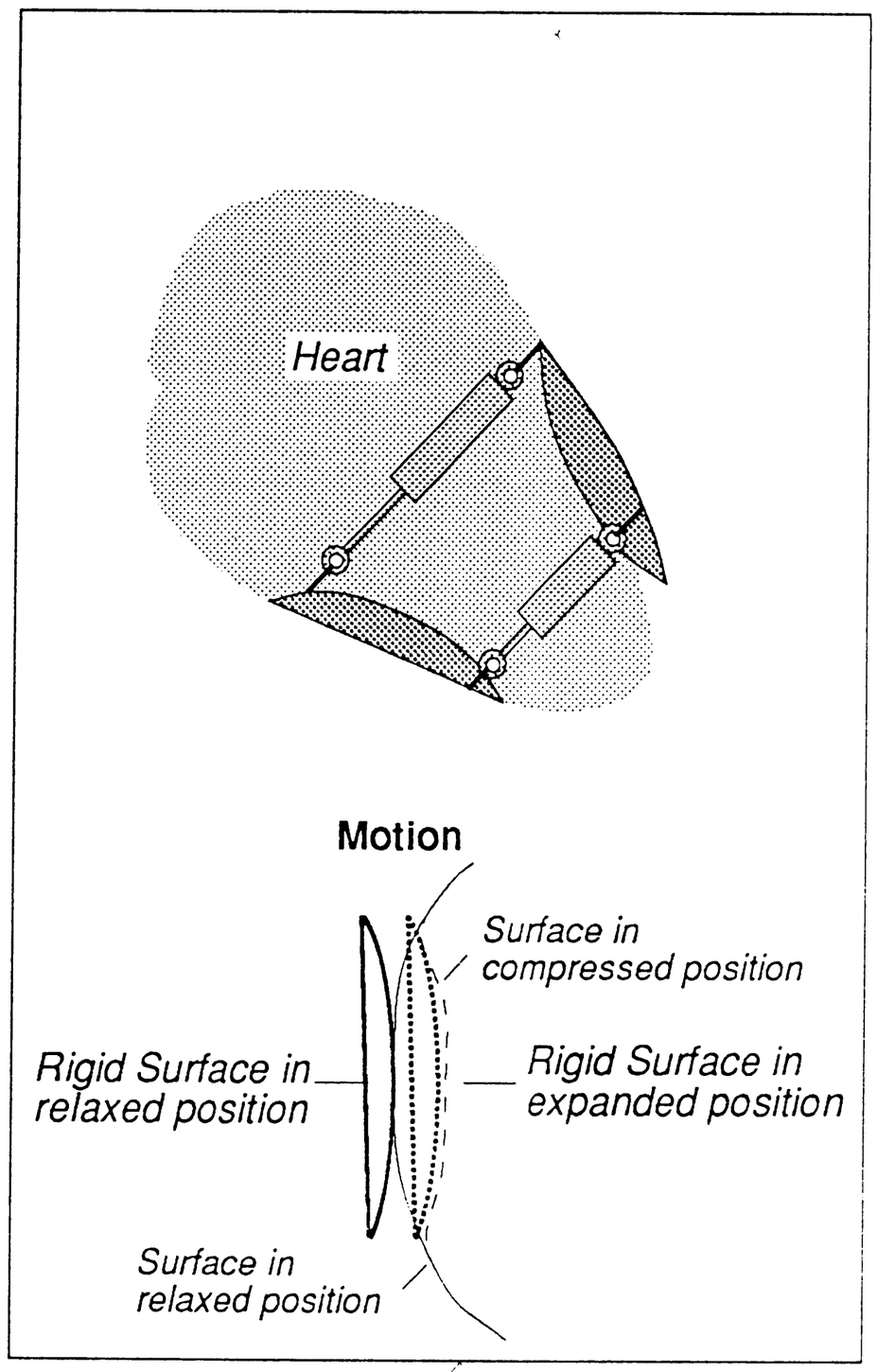

Figure 3.2: Pneumatic Actuation Techniques: Pistons

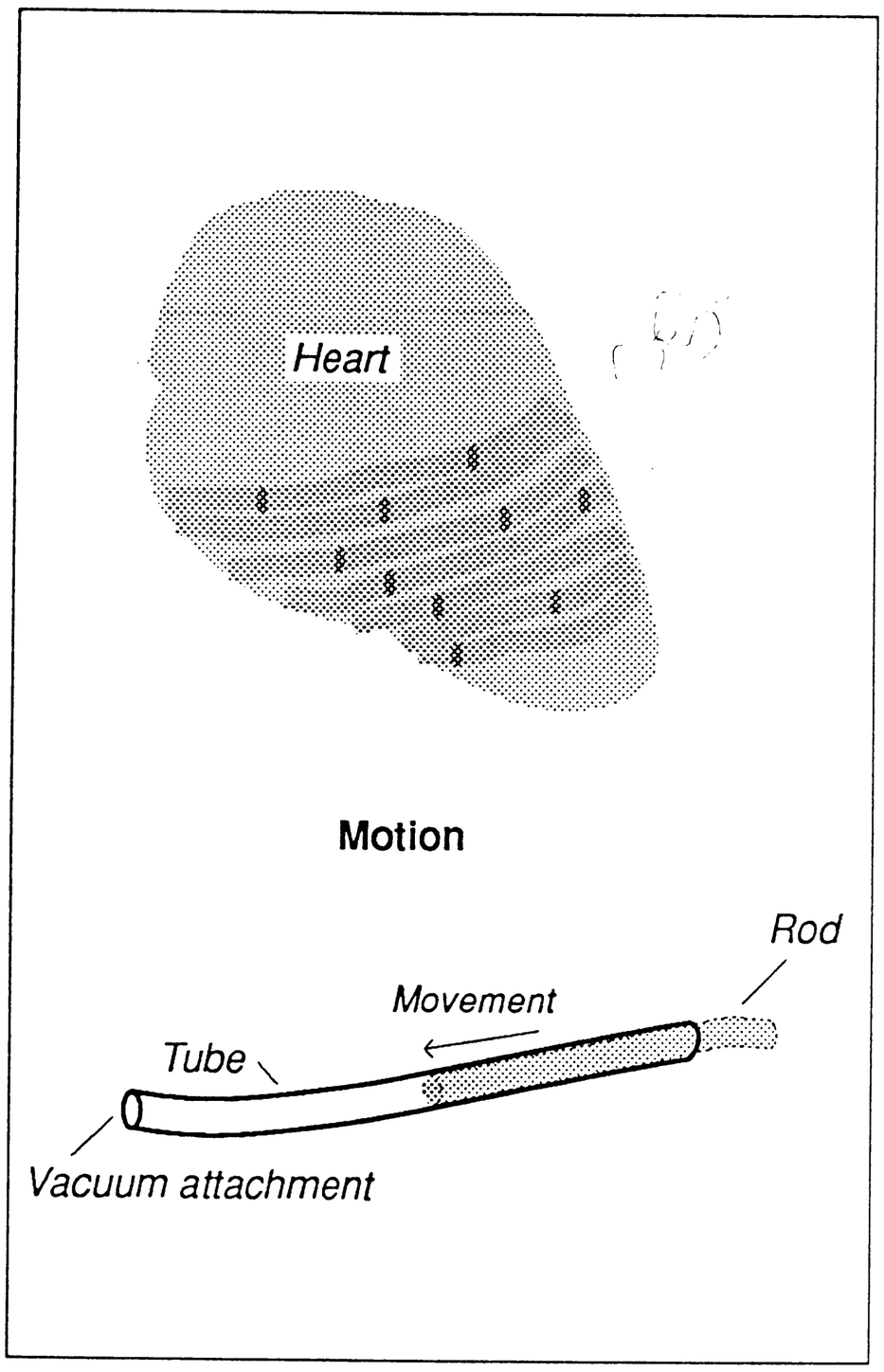

Figure 3.3: Pneumatic Actuation Techniques: Contracting Tubes

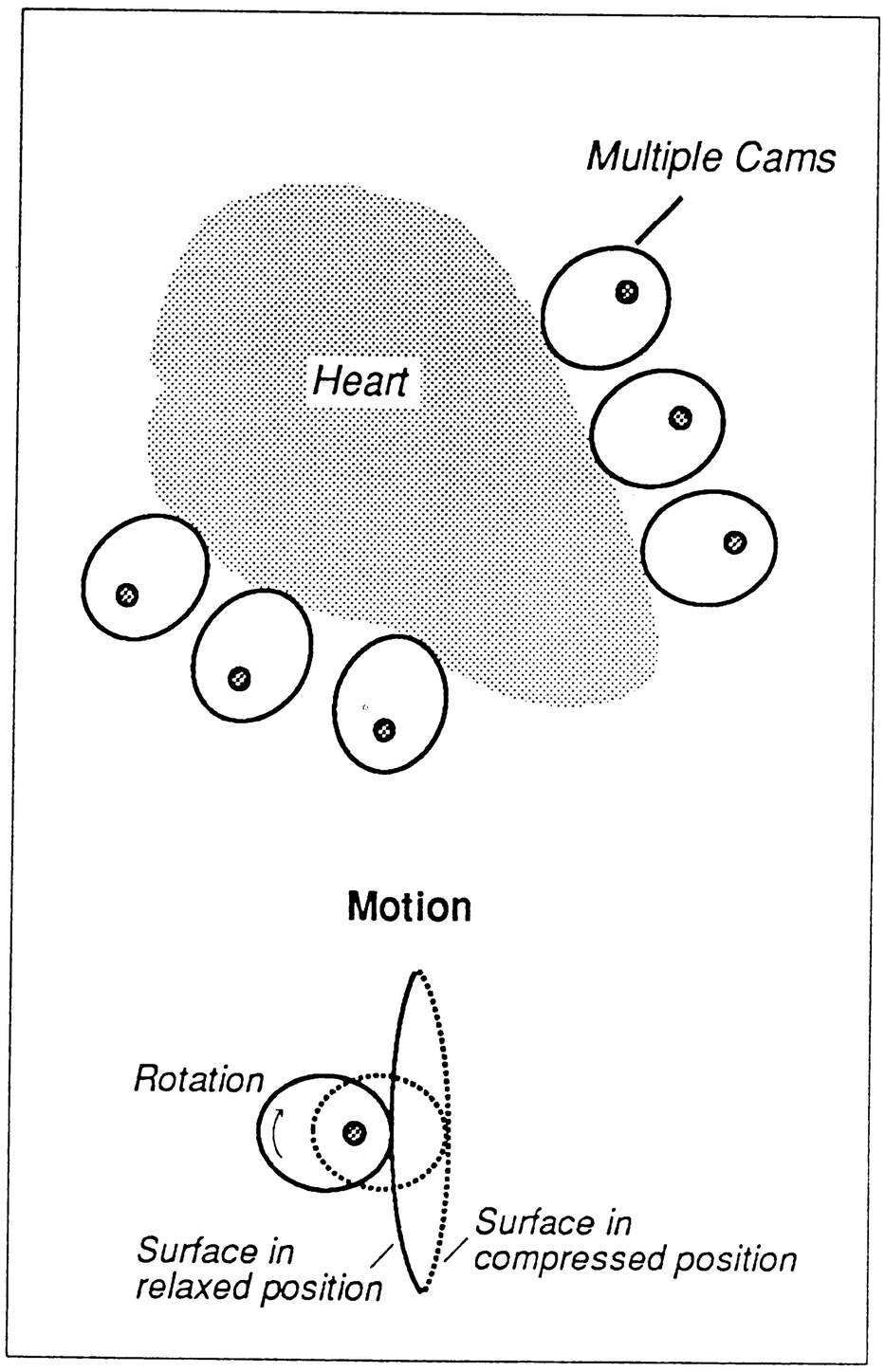

Figure 3.4: Mechanical Actuation Techniques: Cam Method

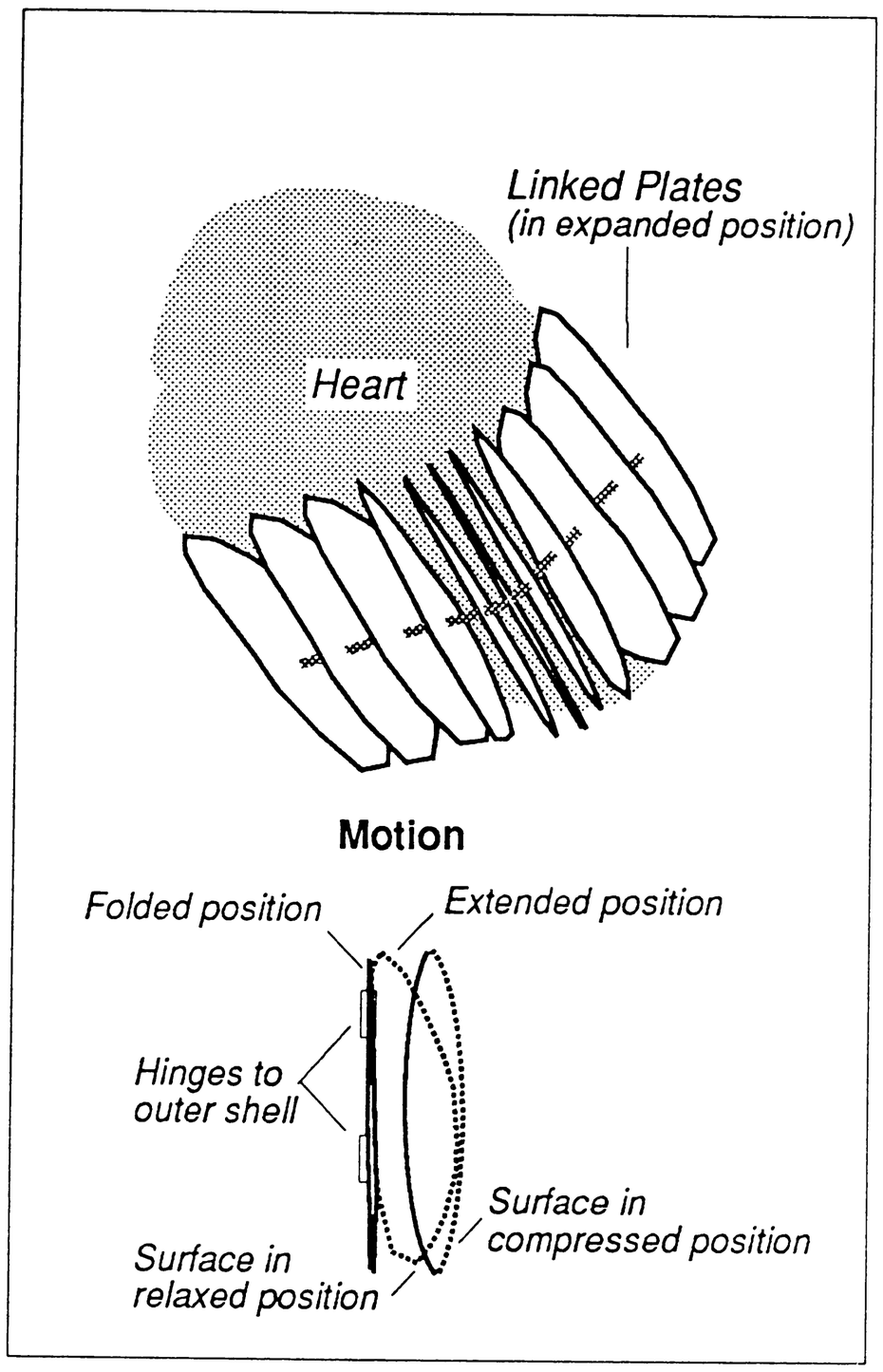

Figure 3.5: Mechanical Actuation Techniques: Linked Plates

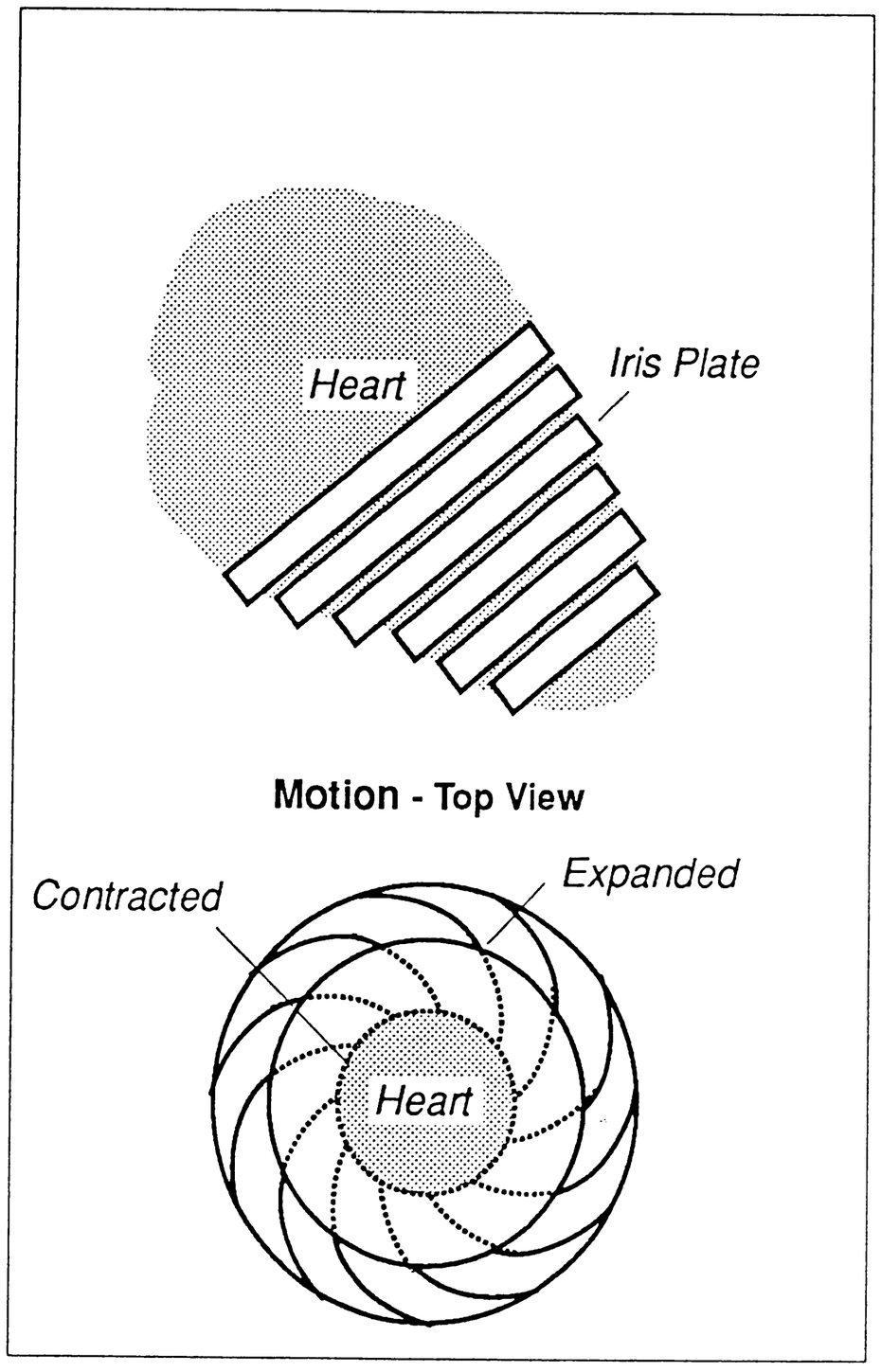

Figure 3.6: Mechanical Actuation Techniques: Iris Plates

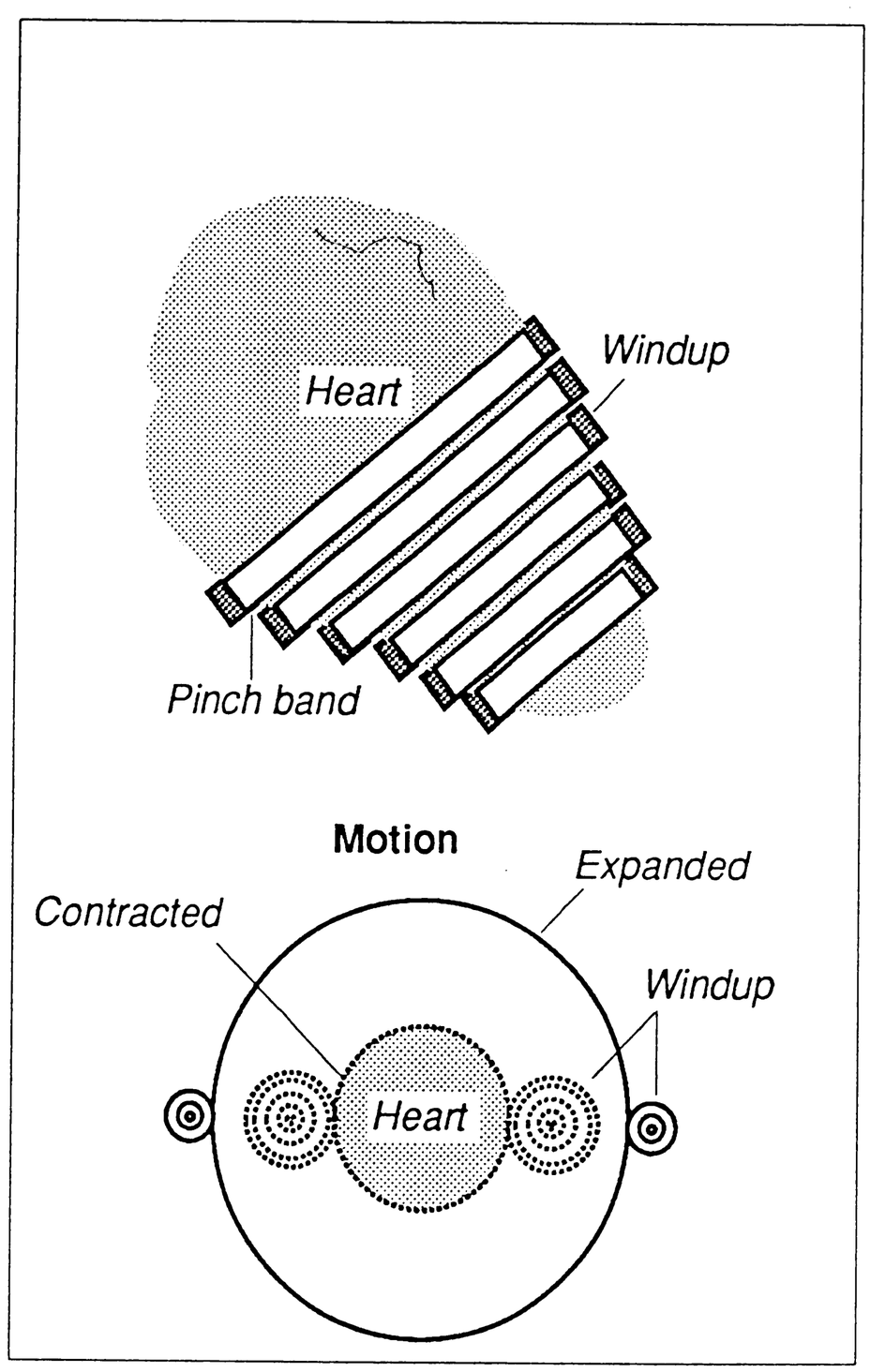

Figure 3.7: Mechanical Actuation Techniques: Windup Bands

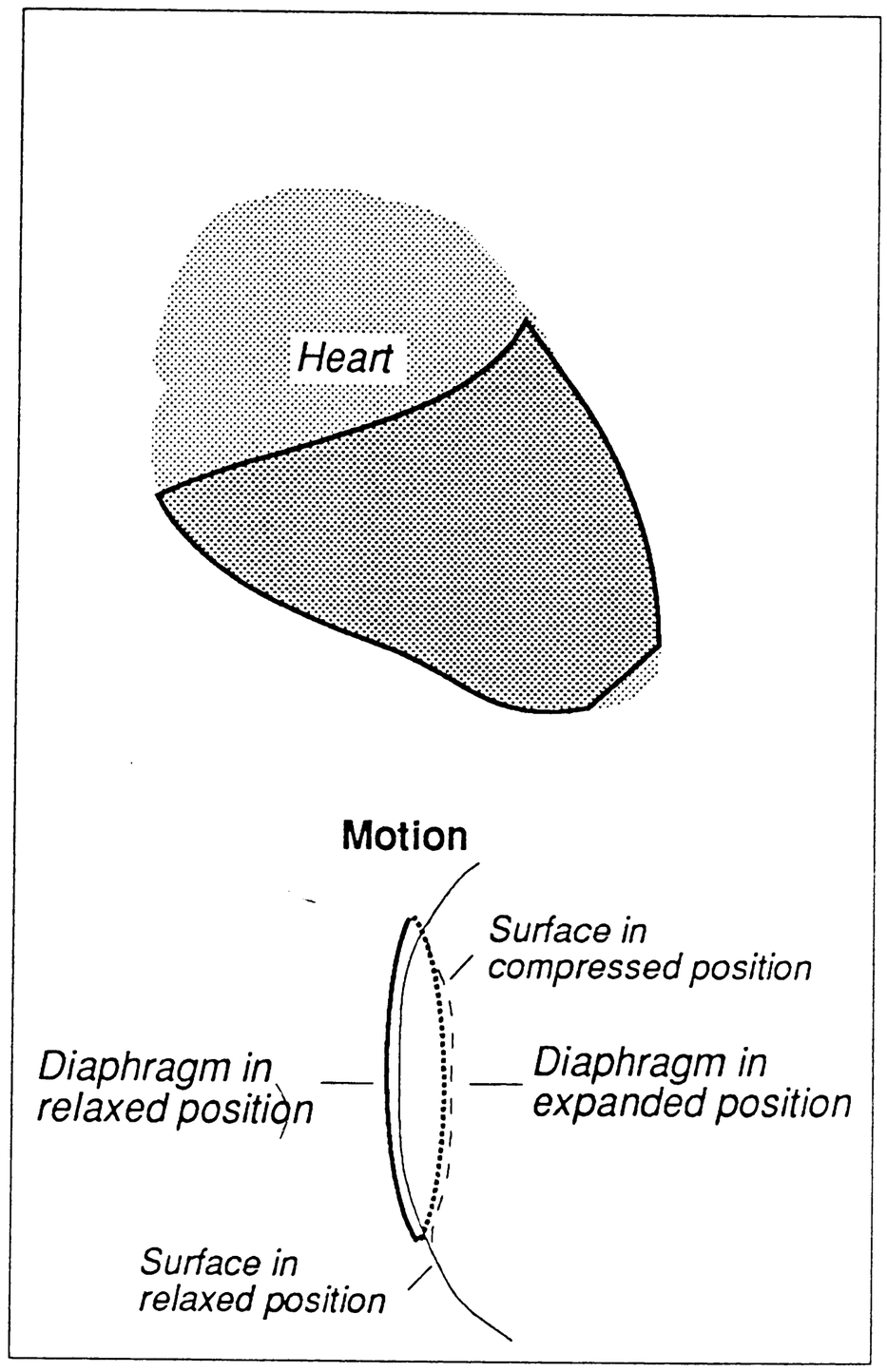

Figure 3.8: Mechanical Actuation Techniques: Rigid/Flexible Diaphragms

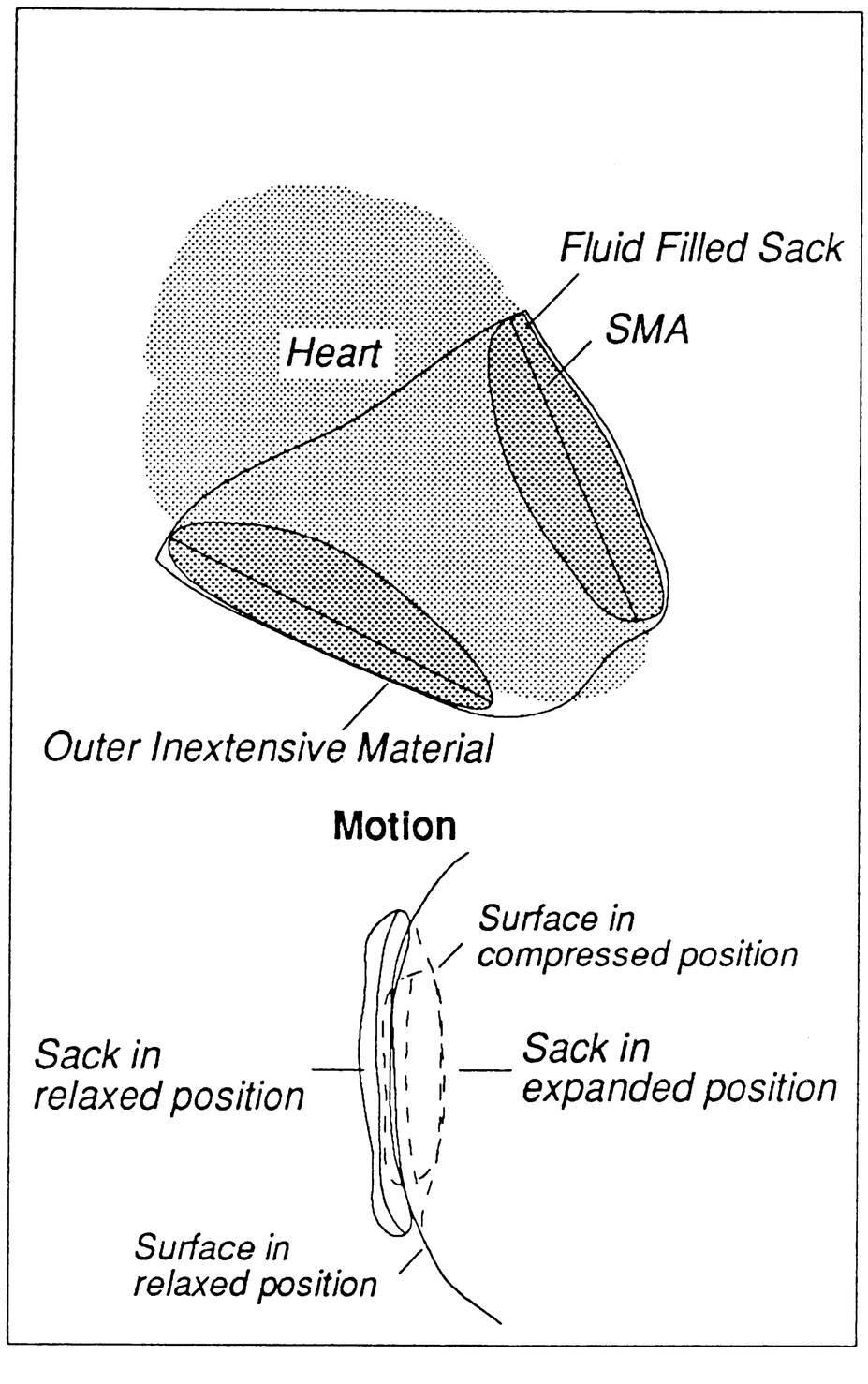

Figure 3.9: Mechanical Actuation Techniques: SMA Actuation

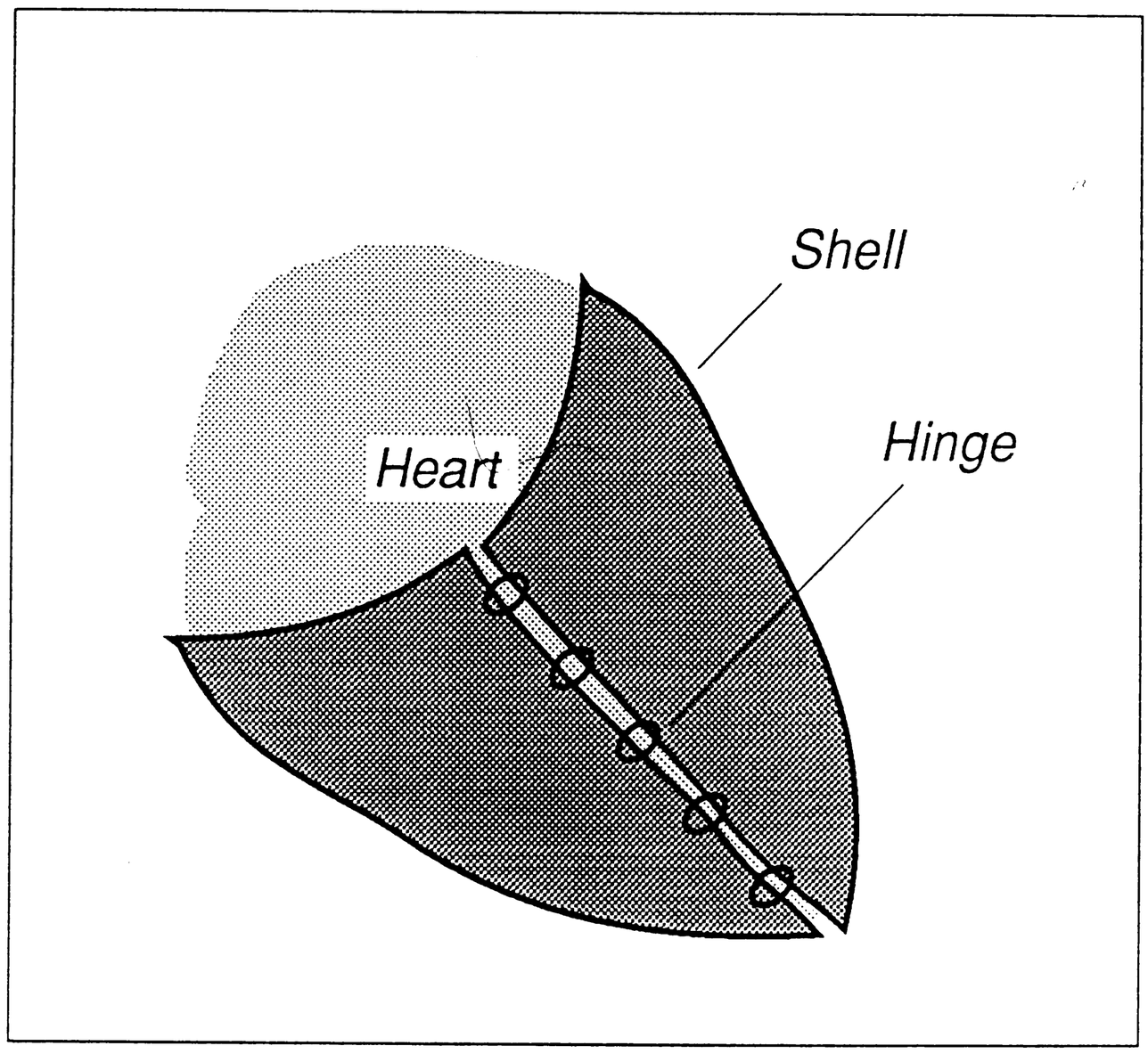

Figure 4.1: Outer Enclosures: Hard Clamshell

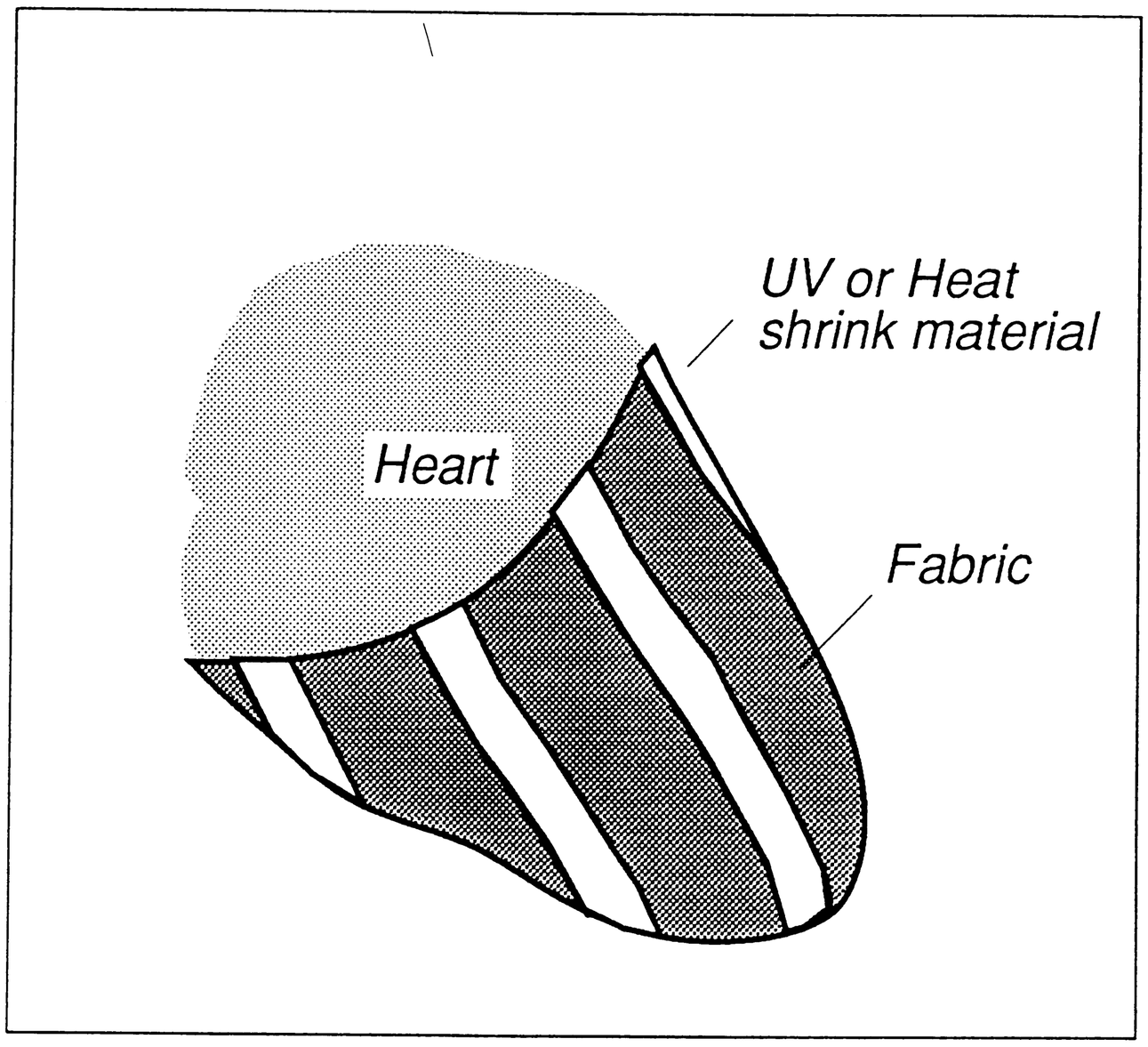

Figure 4.2: Outer Enclosures: Shrinking Plastic-Cloth Composite

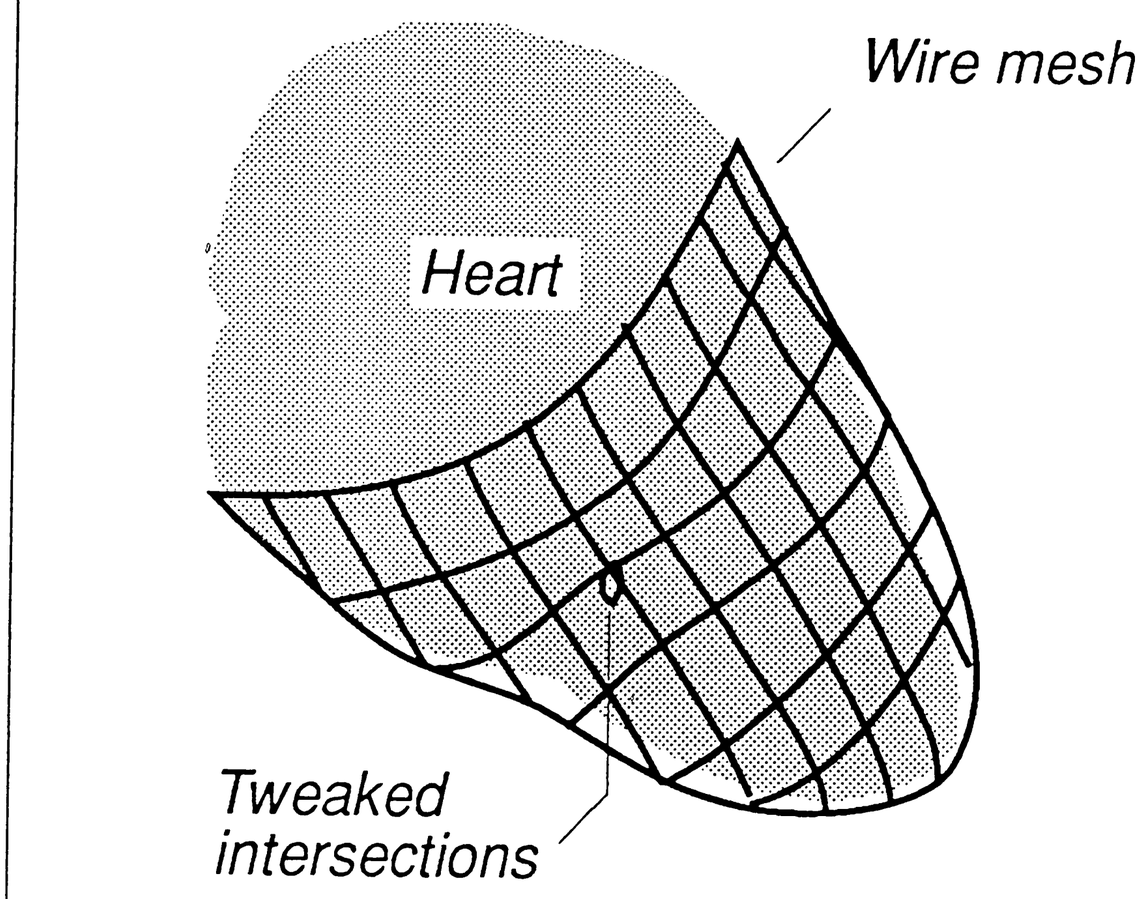

Figure 4.3: Outer Enclosures: Wire Mesh

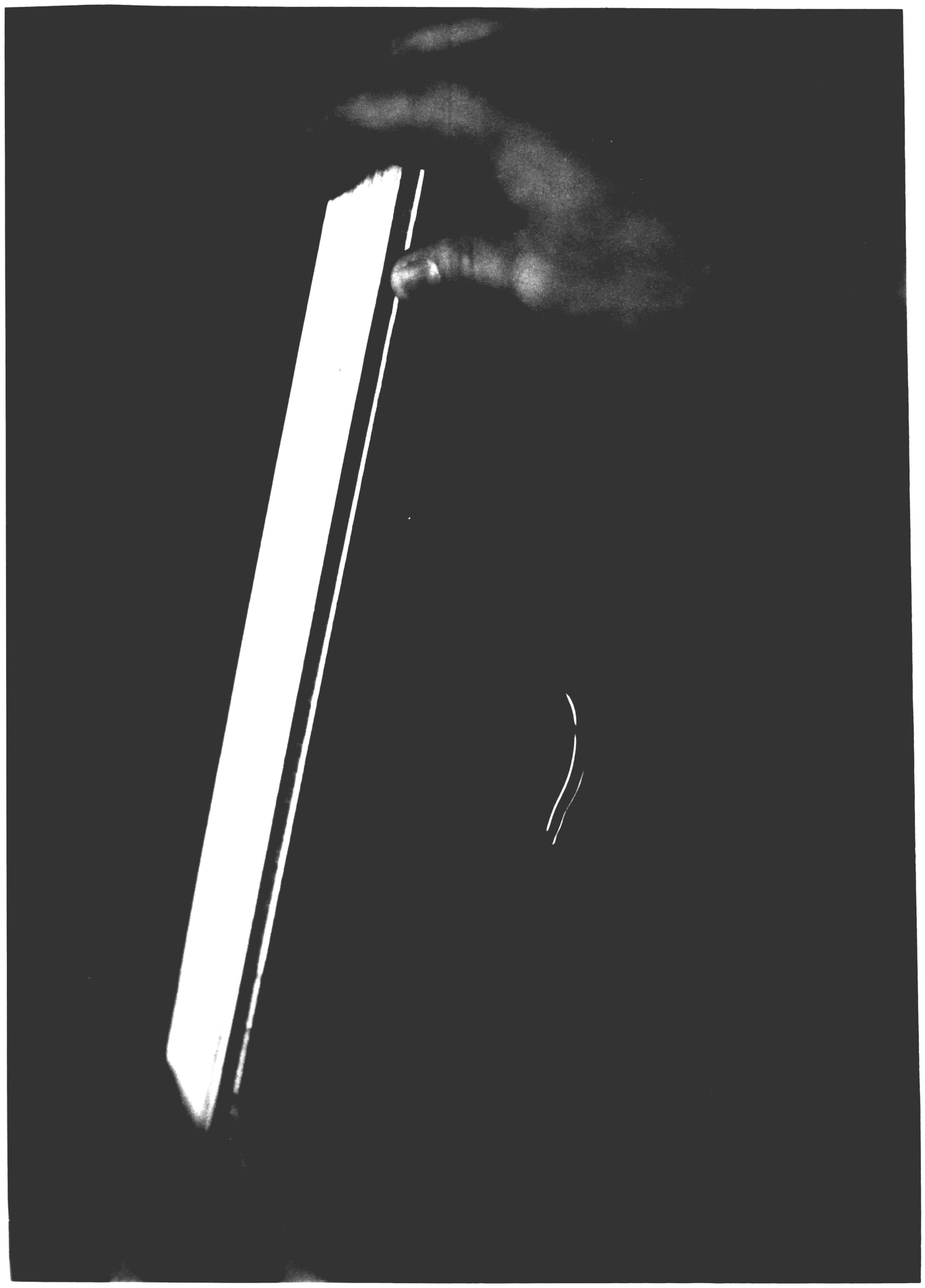

Figure 7.1: Metal Plane

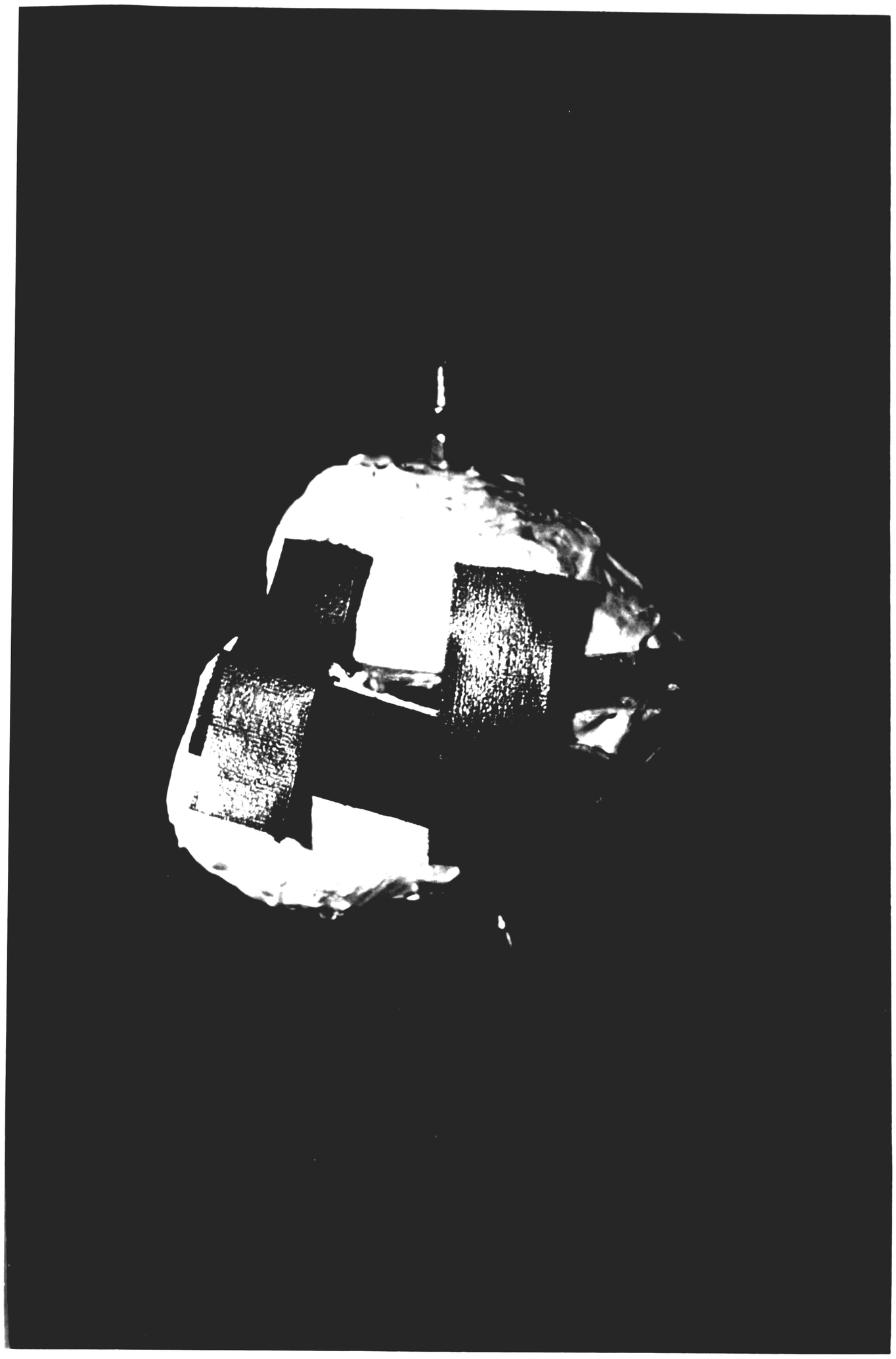

Figure 7.2: First Prototype MBAD

Figure 7.3: Bellows Foot Pump

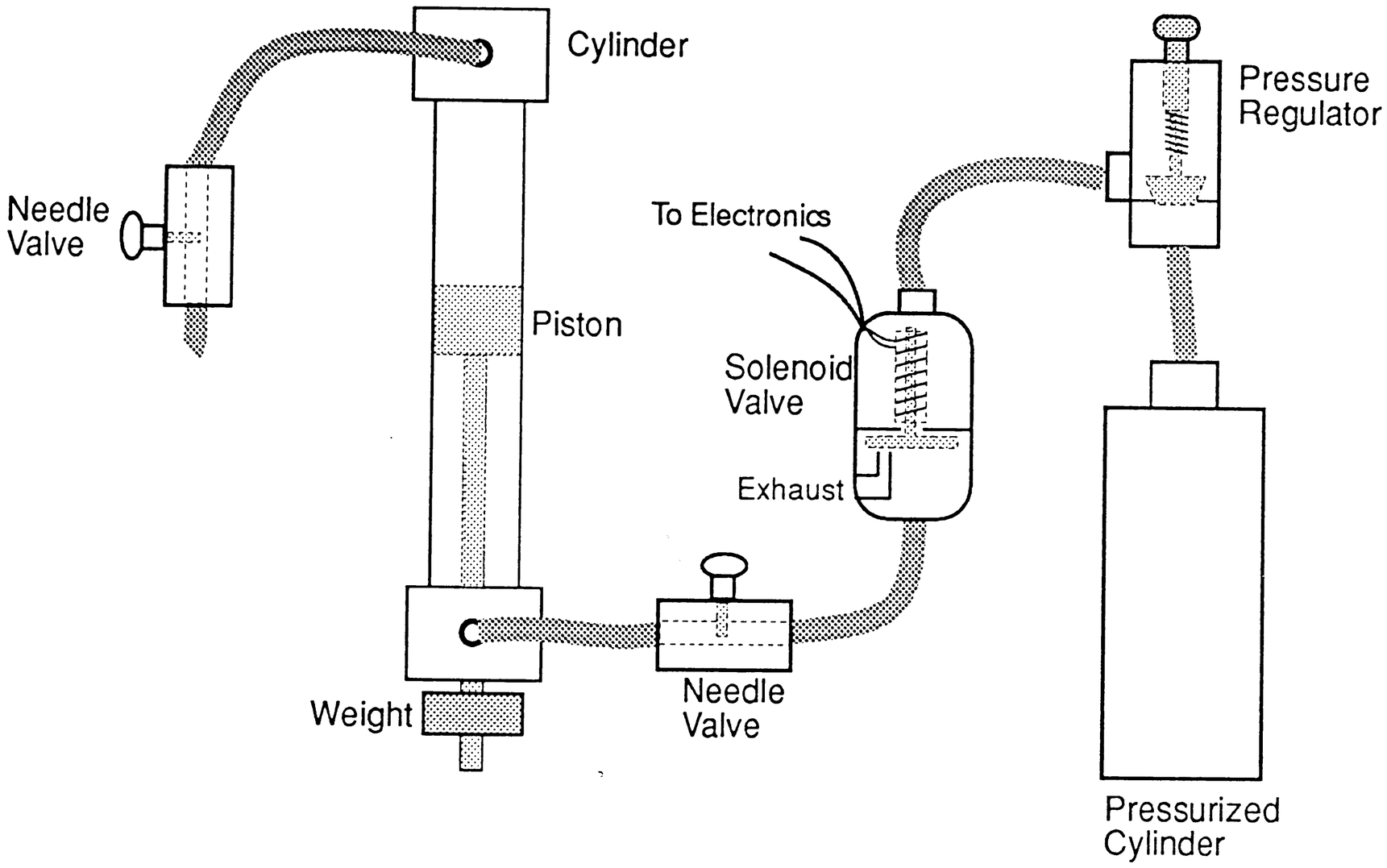

Figure 8.1: Dipping Machine: Schematic of Automatic Dipping Machine

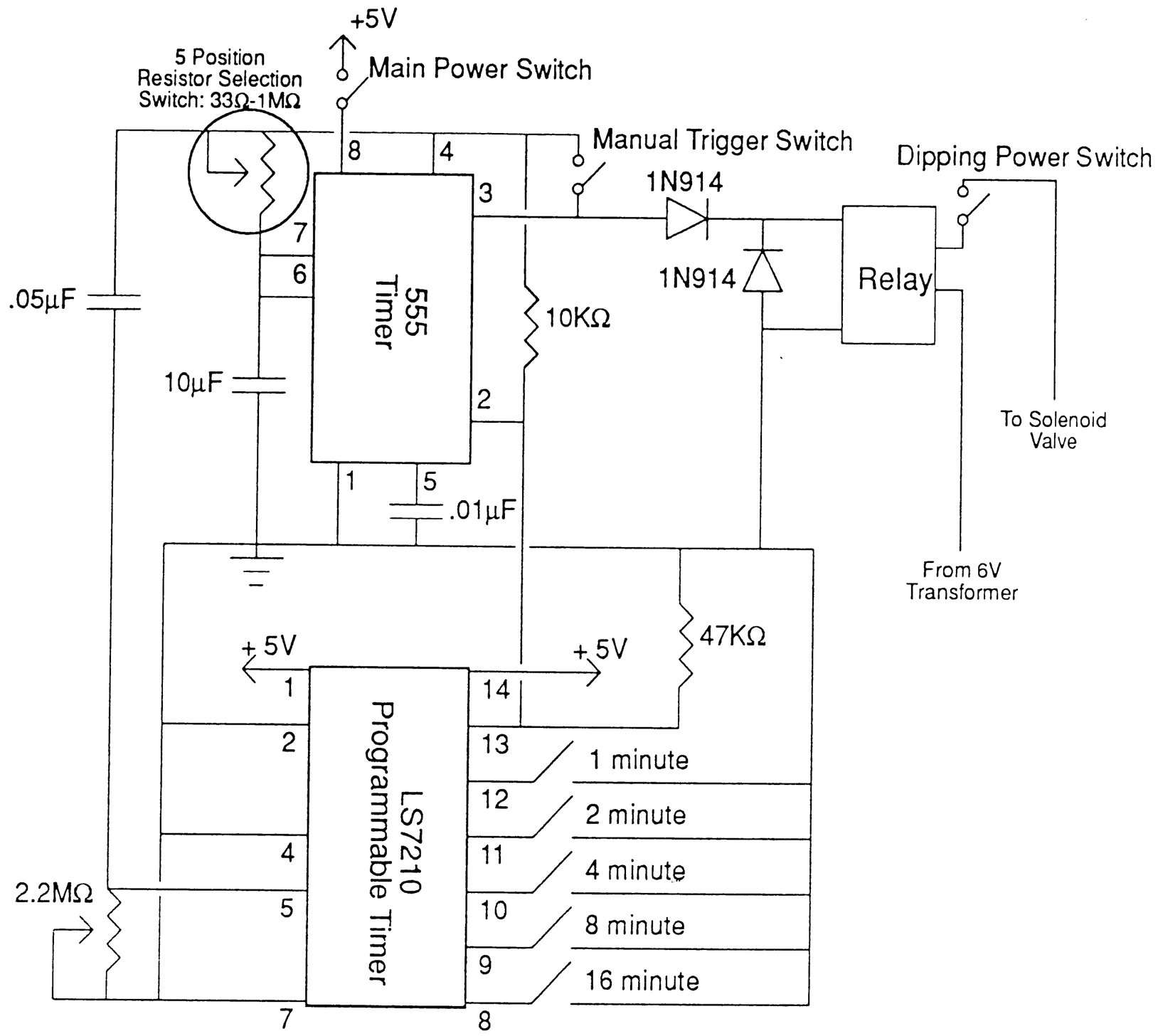

Figure 8.2: Dipping Machine: Schematic of Timing Circuitry

Figure 8.3: Dipping Machine

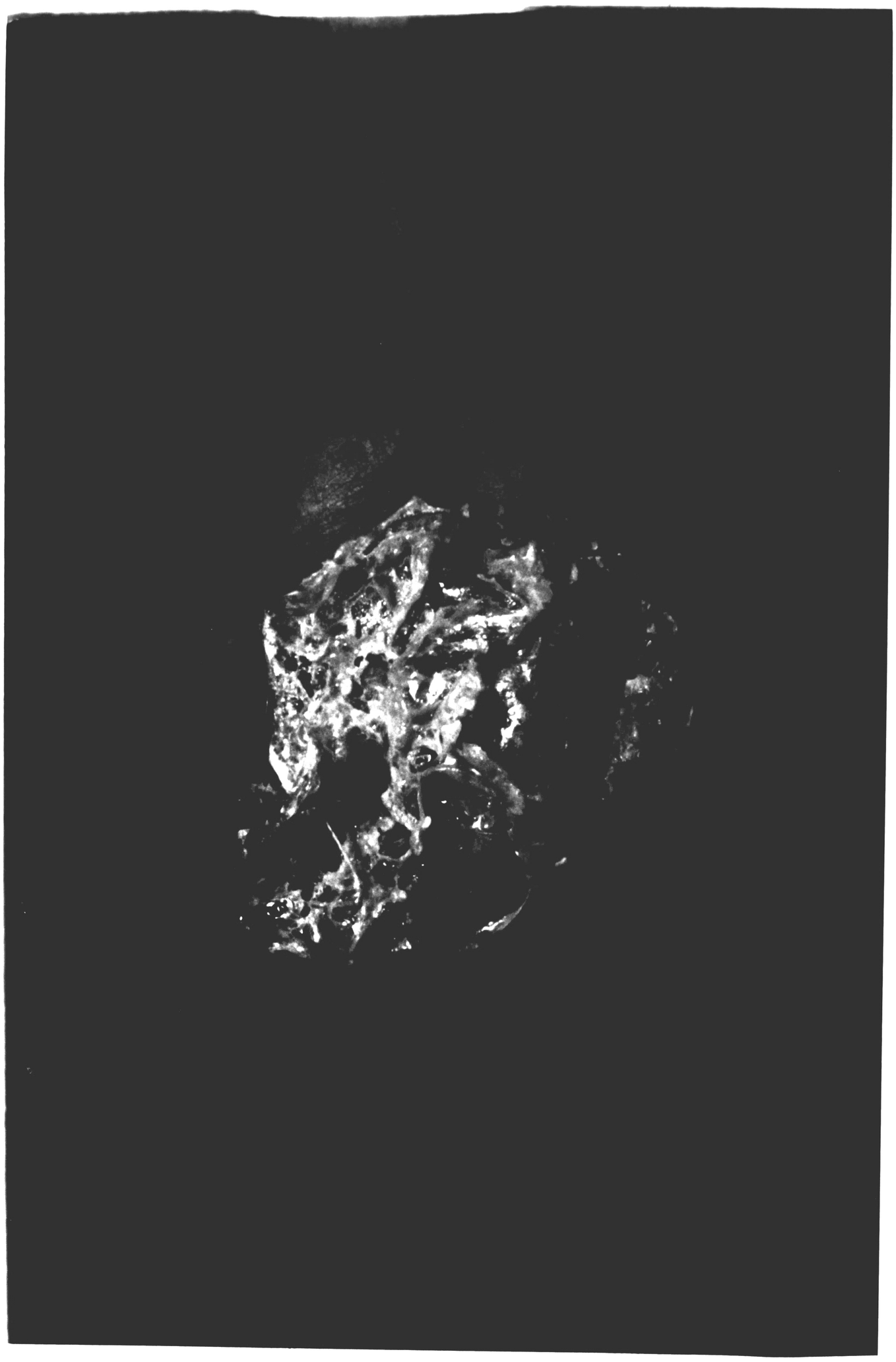

Figure 9.1: First: Hytrel Shell

Figure 9.2: Second: Hytrel Shell

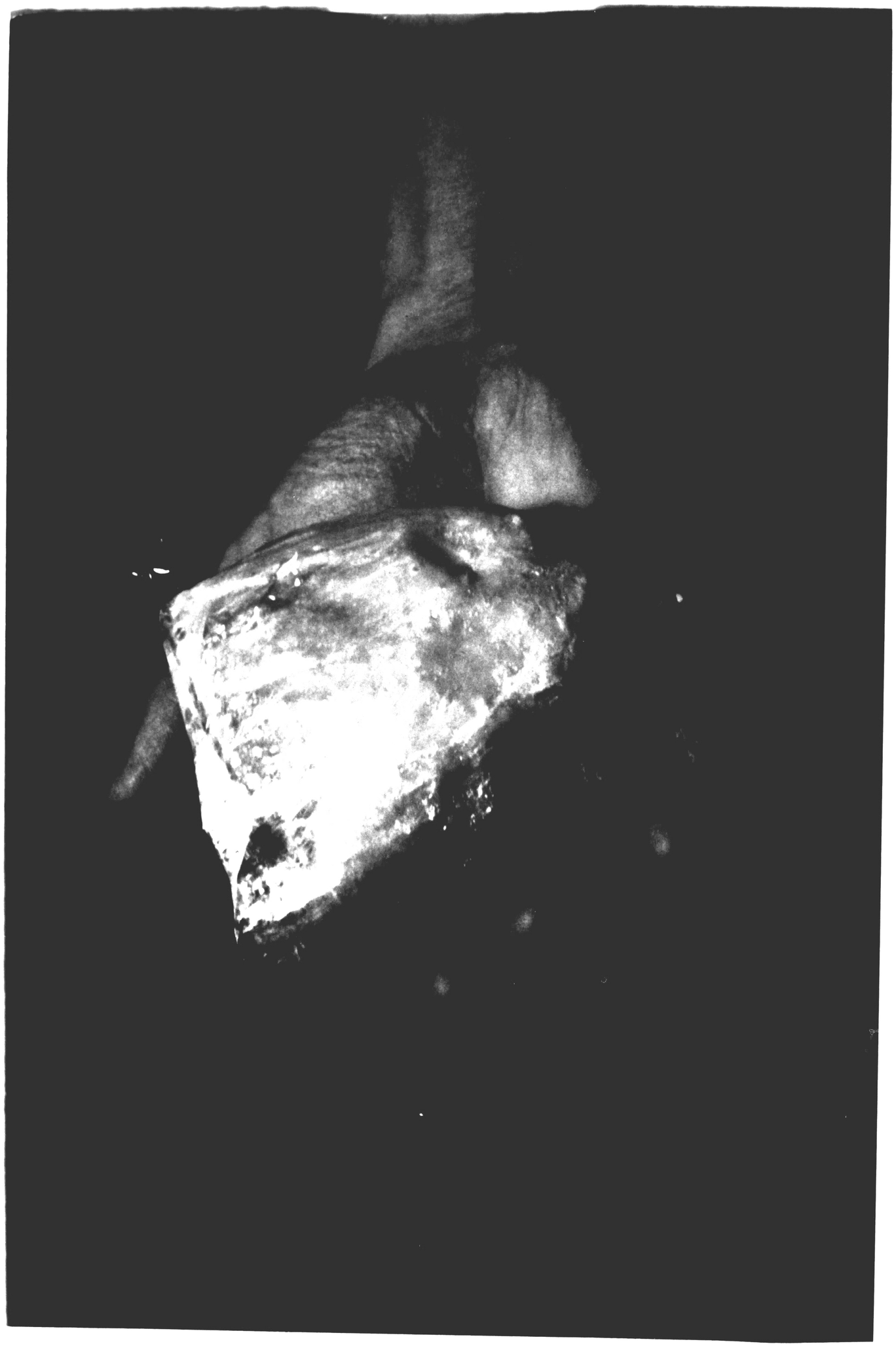

Figure 9.3: Third: Hytrel Shell With Attempted Bladders

Figure 9.4: Fourth: Silicon Shell

Figure 11.1: Stainless Steel Dipping Container With Thermometer Attached

Figure 11.2: First MBAD

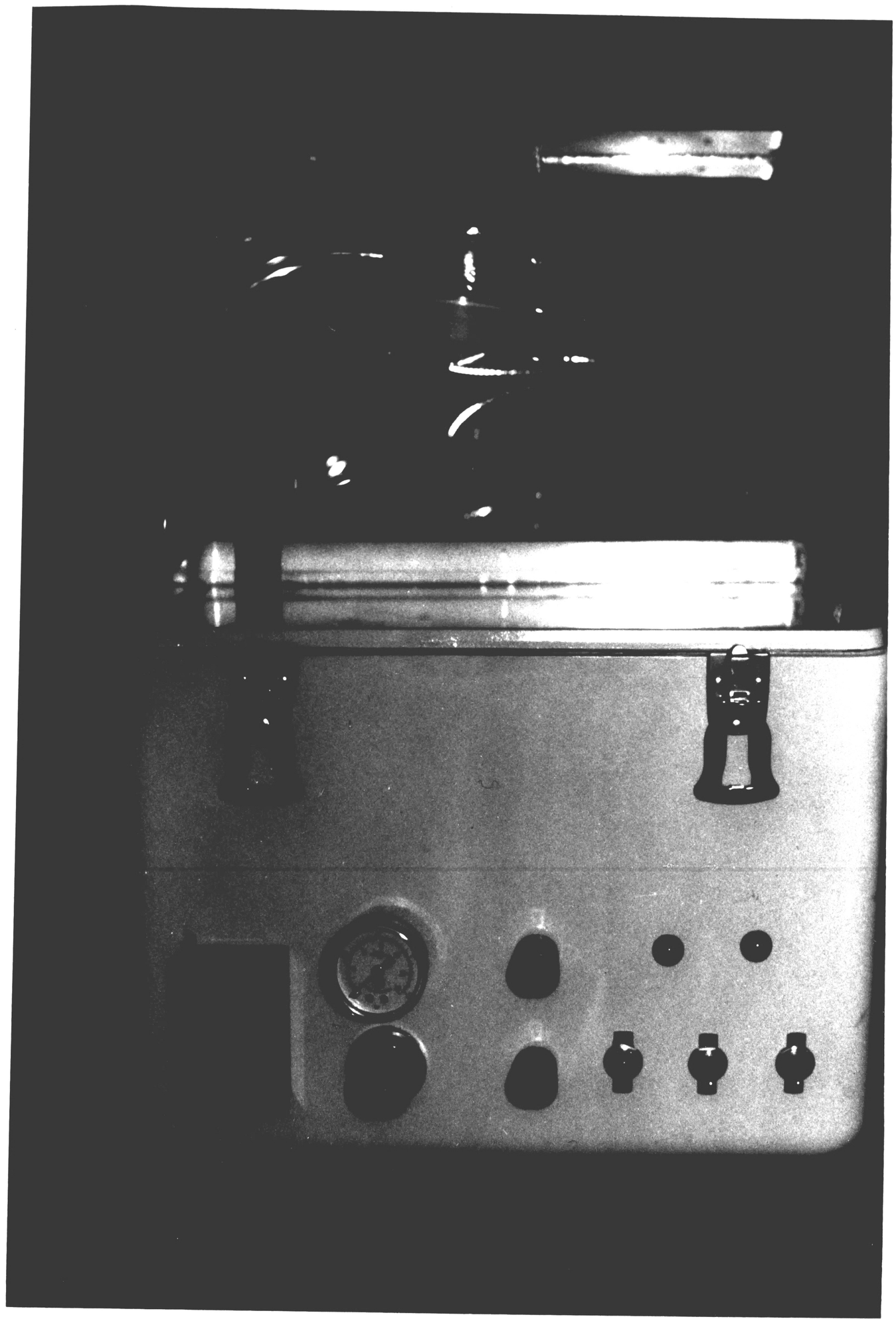

Figure 12.1: Pumping Machine

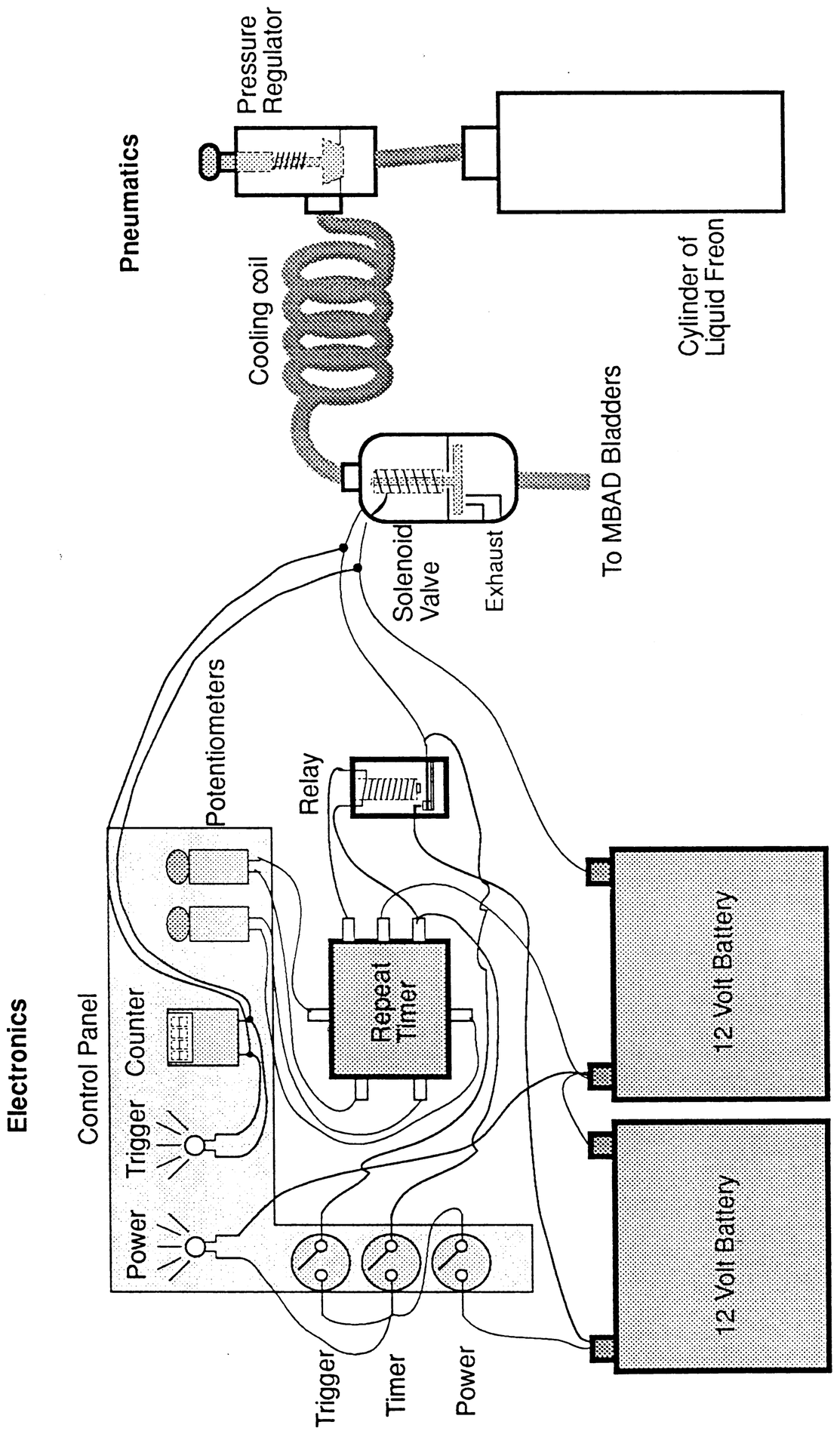

Figure 12.2: Schematic of MBAD Pumping System

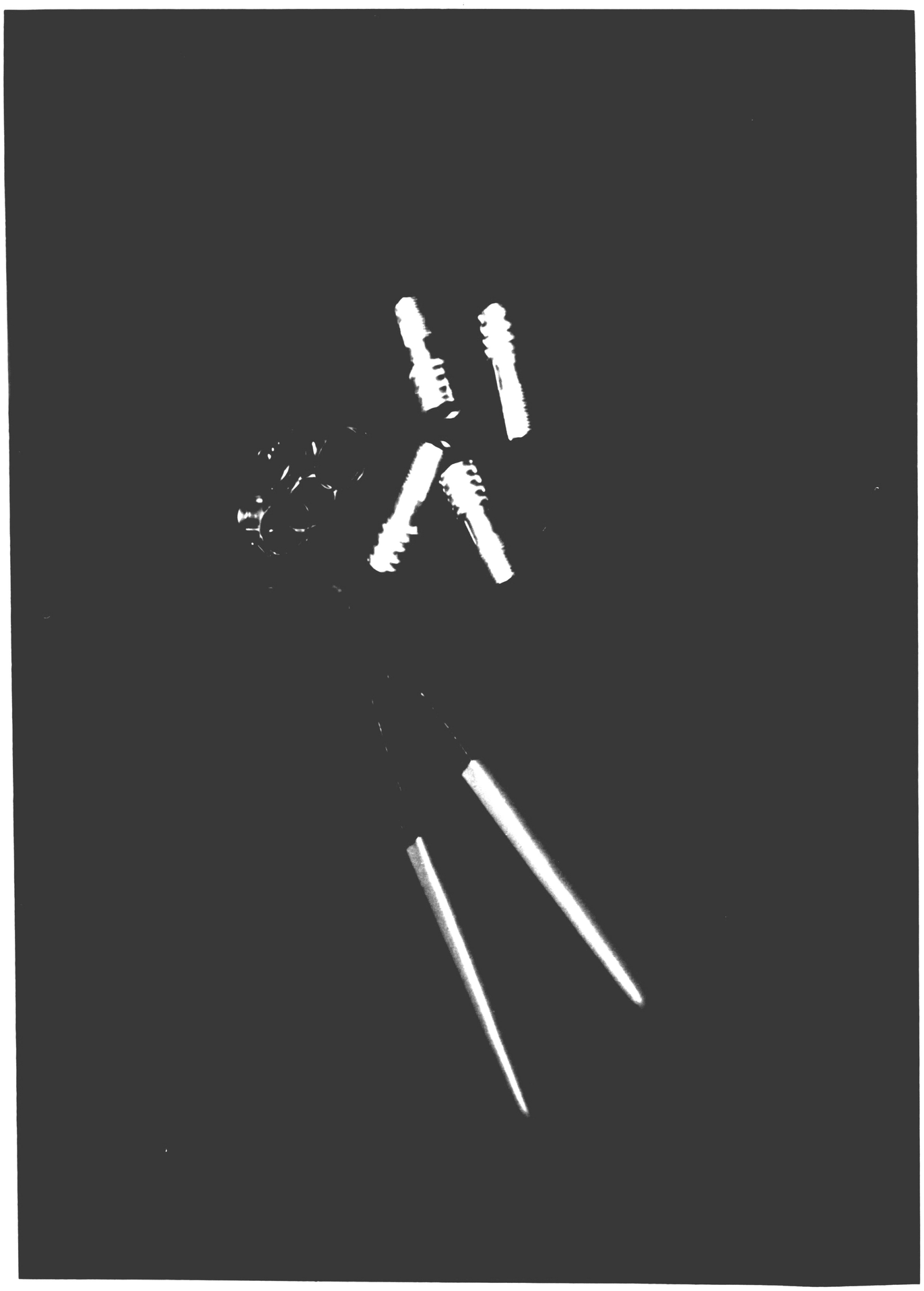

Figure 13.1: Aluminum Fittings and Stainless Steel Clamps

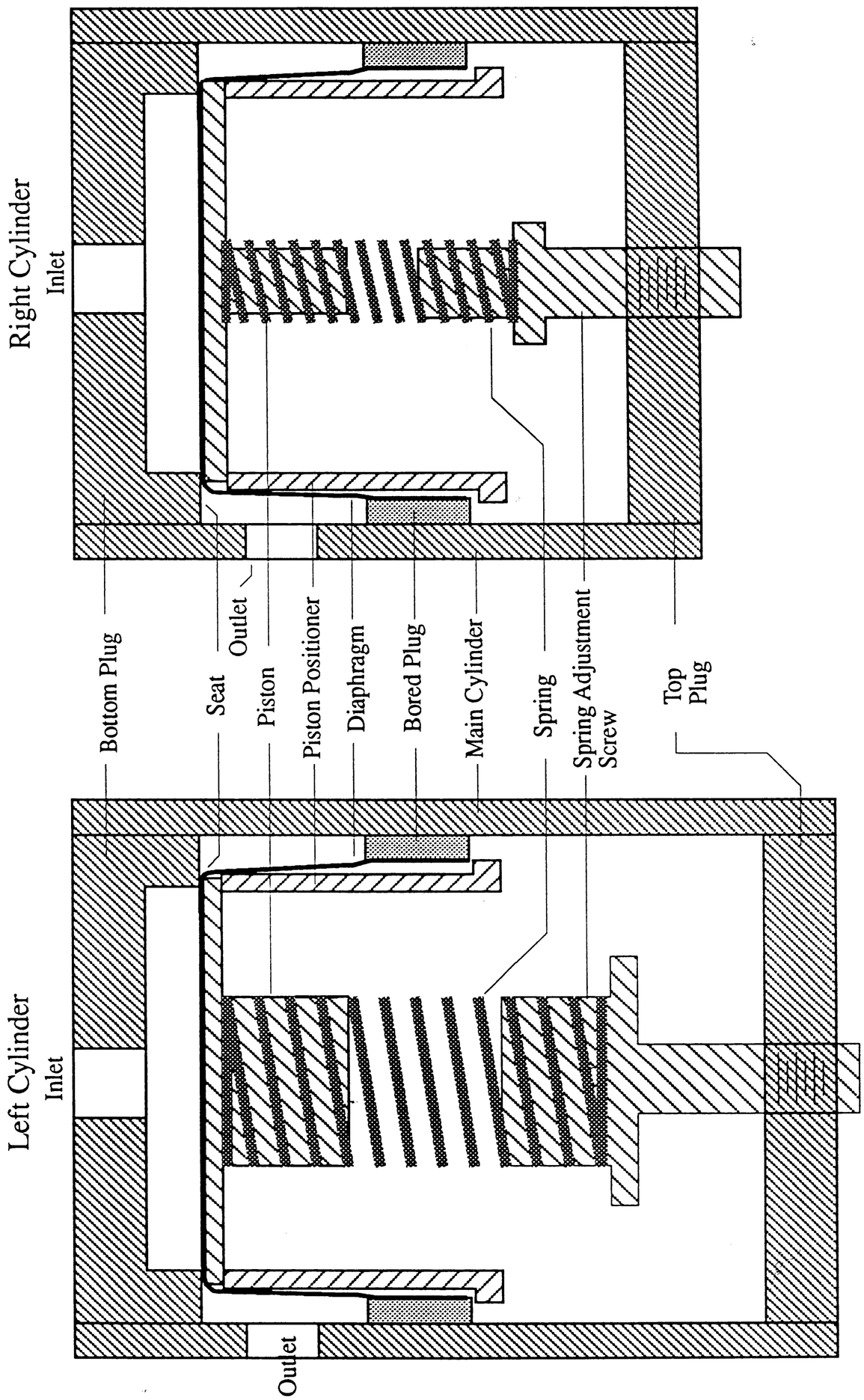

Figure 14.1: Arterial Pressure Cylinders

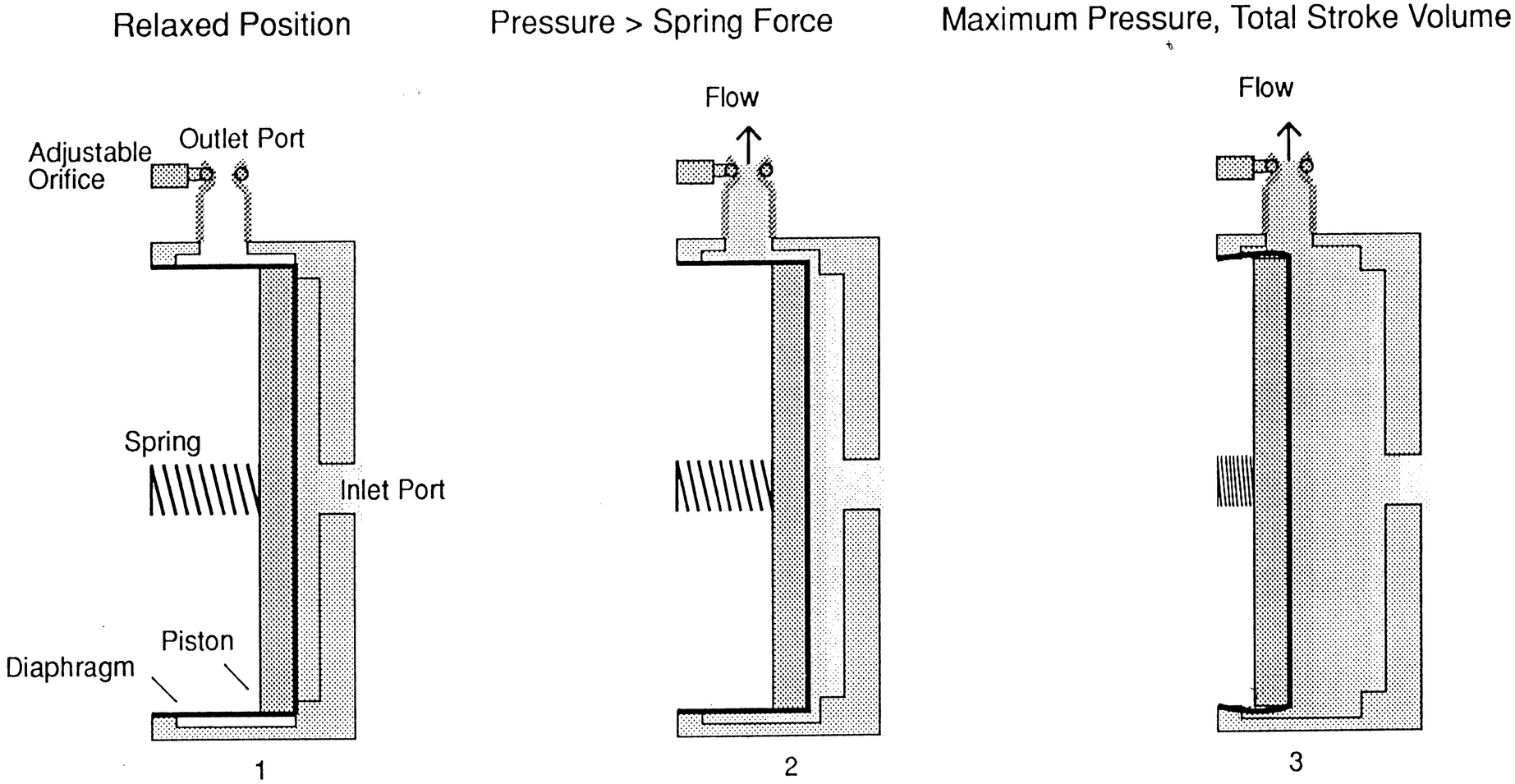

Figure 14.2: Piston Cycle

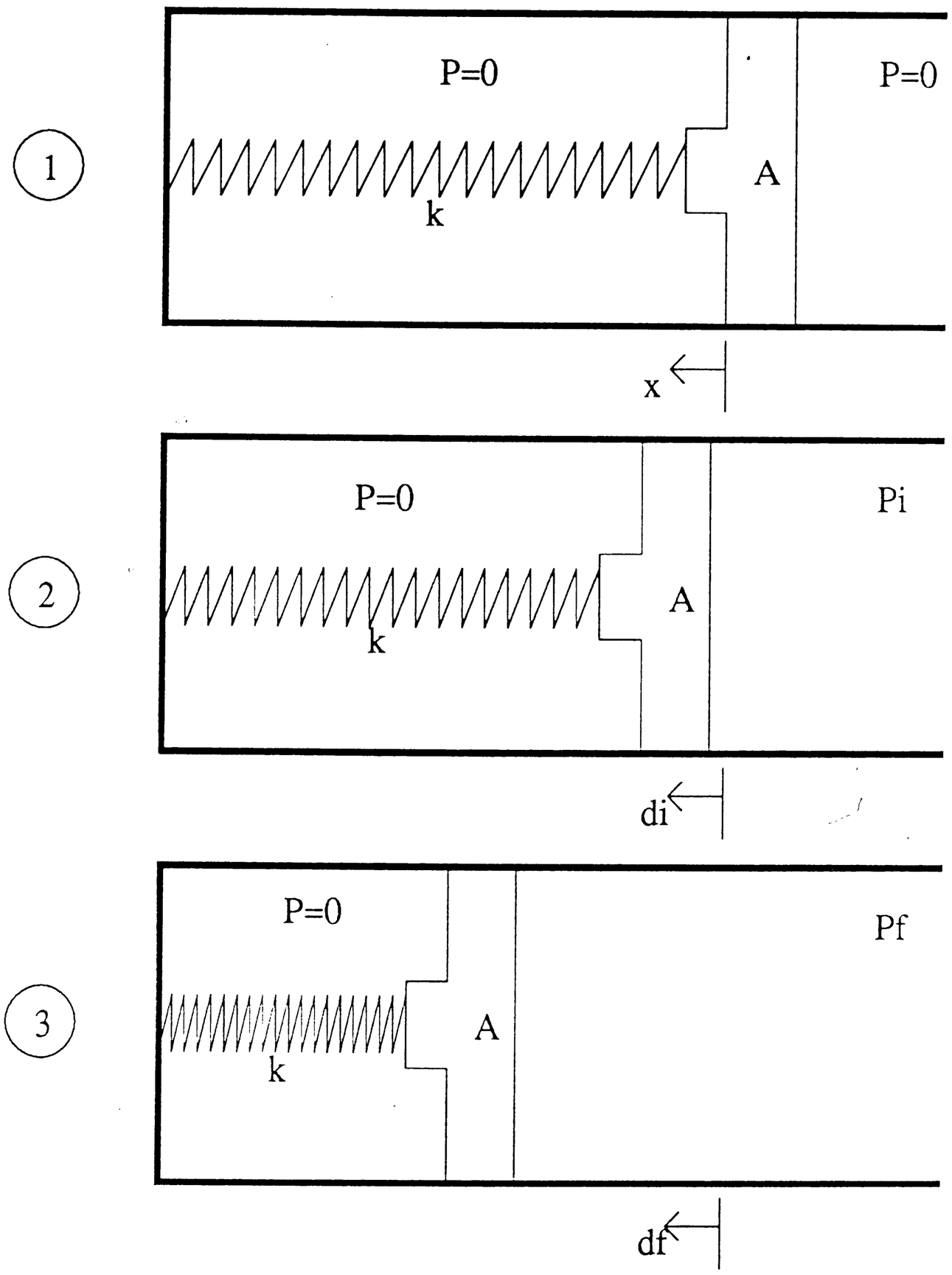

Figure 14.3: Schematic of Pumping Cycle

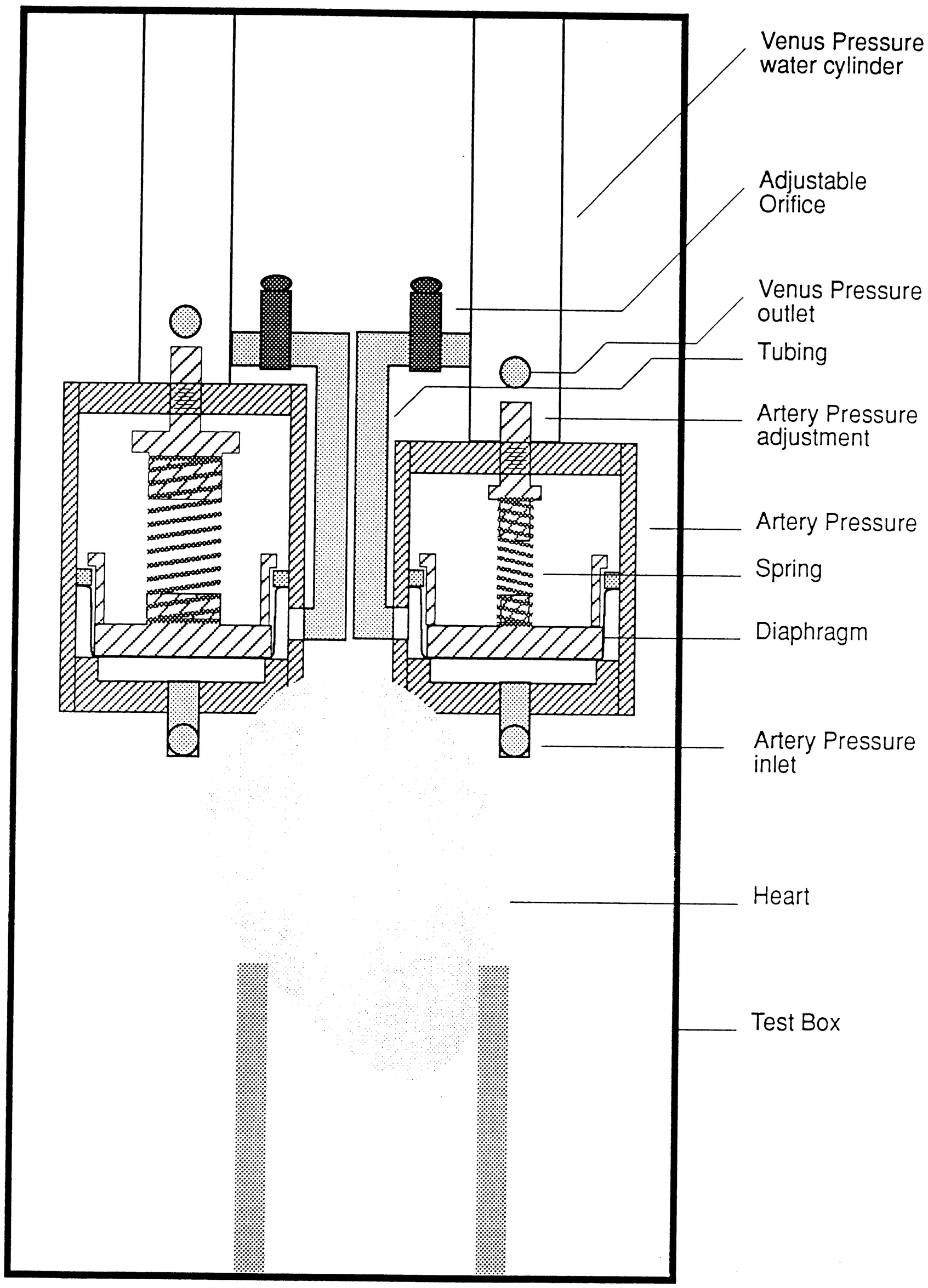

Figure 14.4: Test Stand Schematic

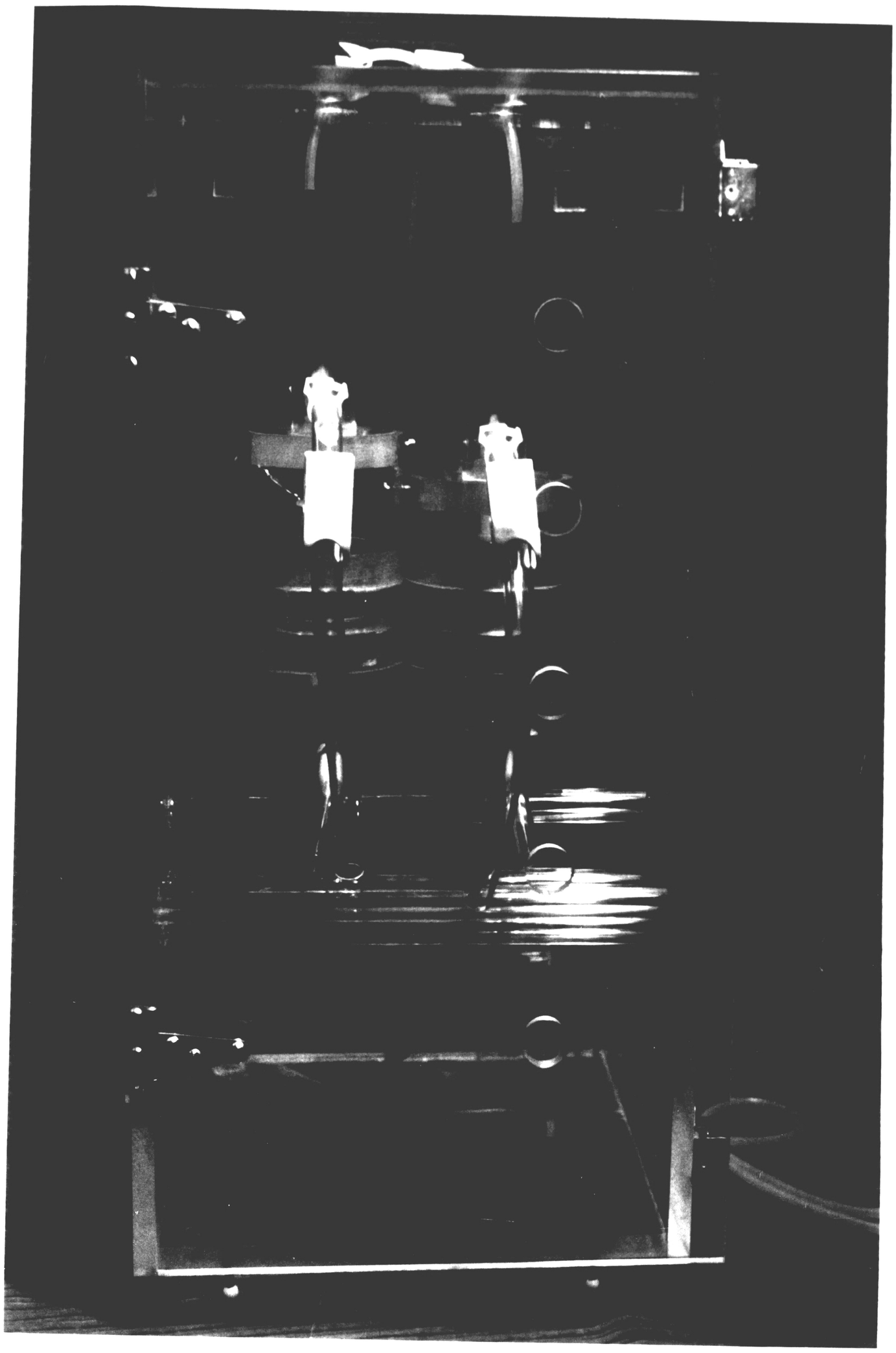

Figure 14.5: Test Stand

Figure 15.1: New Mold

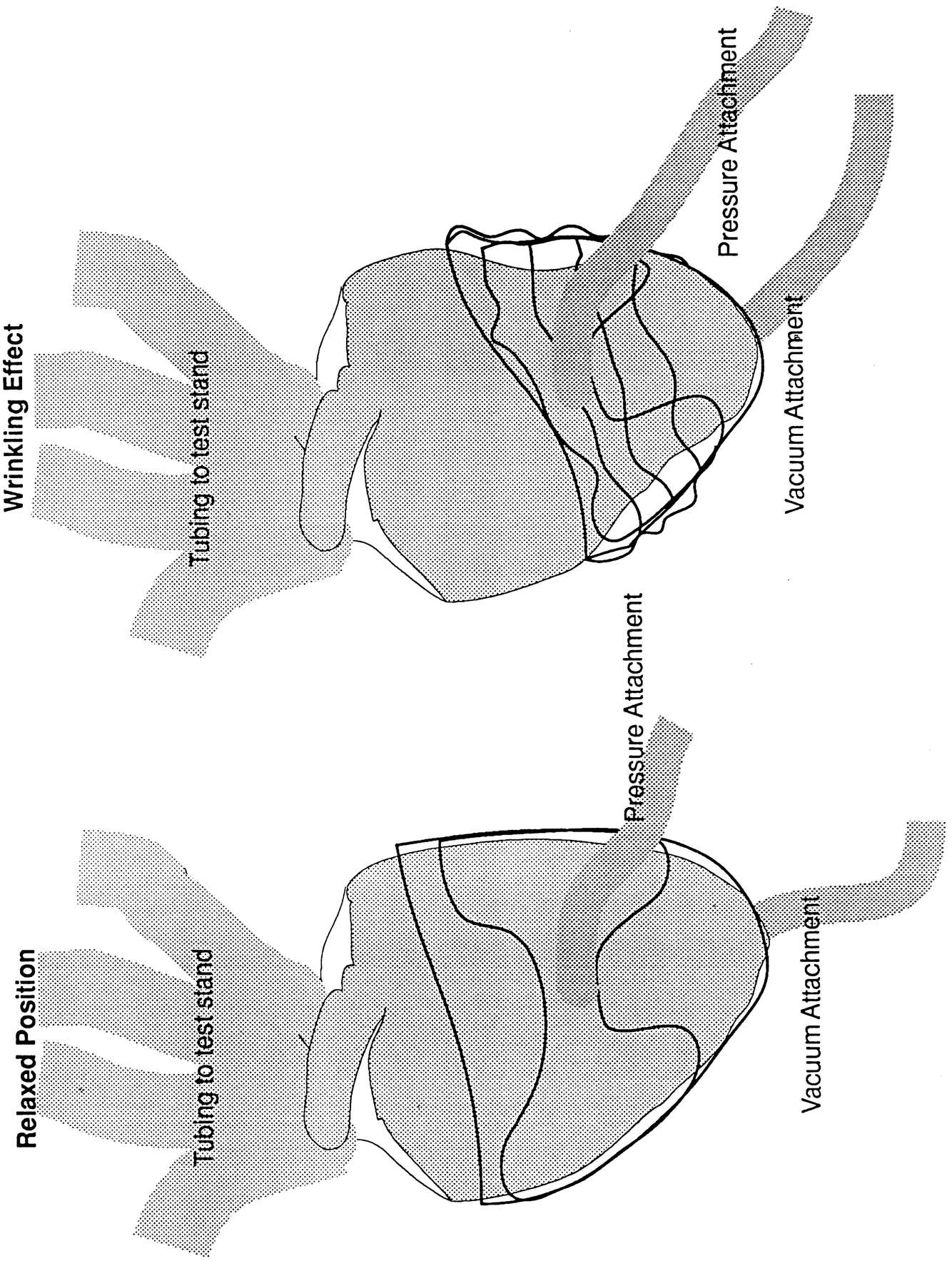

Figure 15.2: Wrinkling Effect of MBAD

Figure 15.3: Marked Shell For Correct Bladder Placement

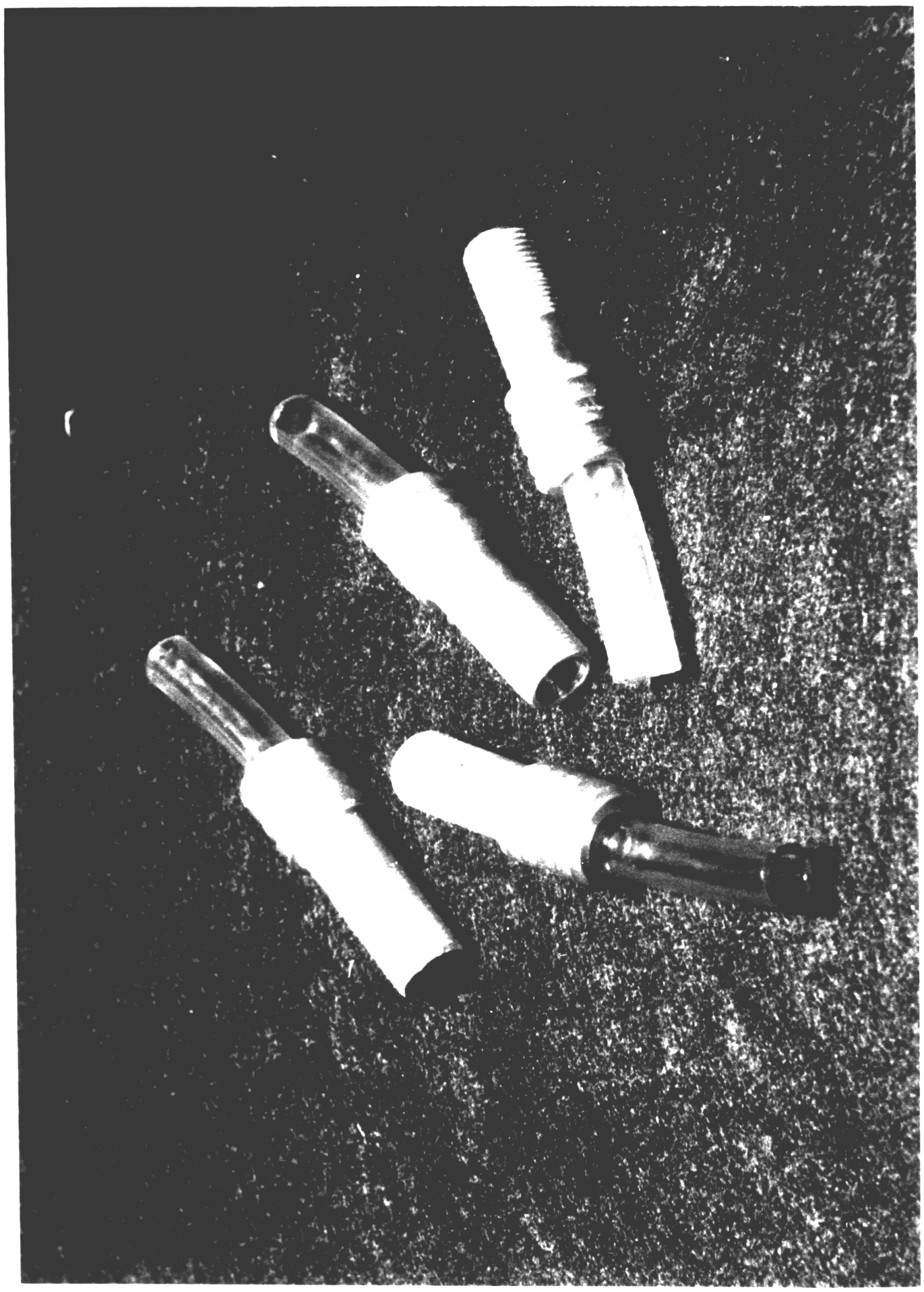

Figure 15.4: Aluminum Fittings With Tubing Extensions

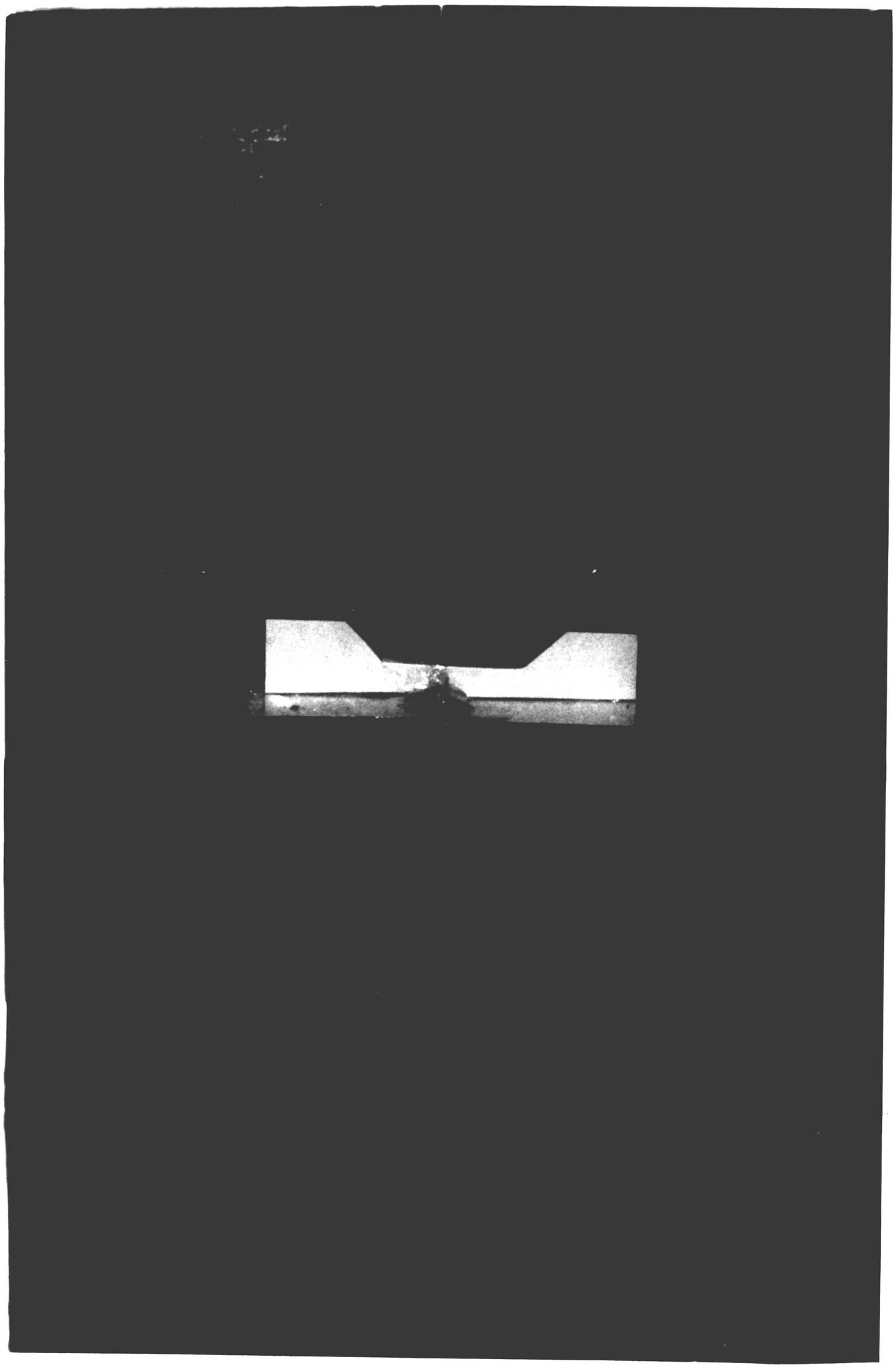

Figure 15.5: Dipping Machine: Automatic Cover

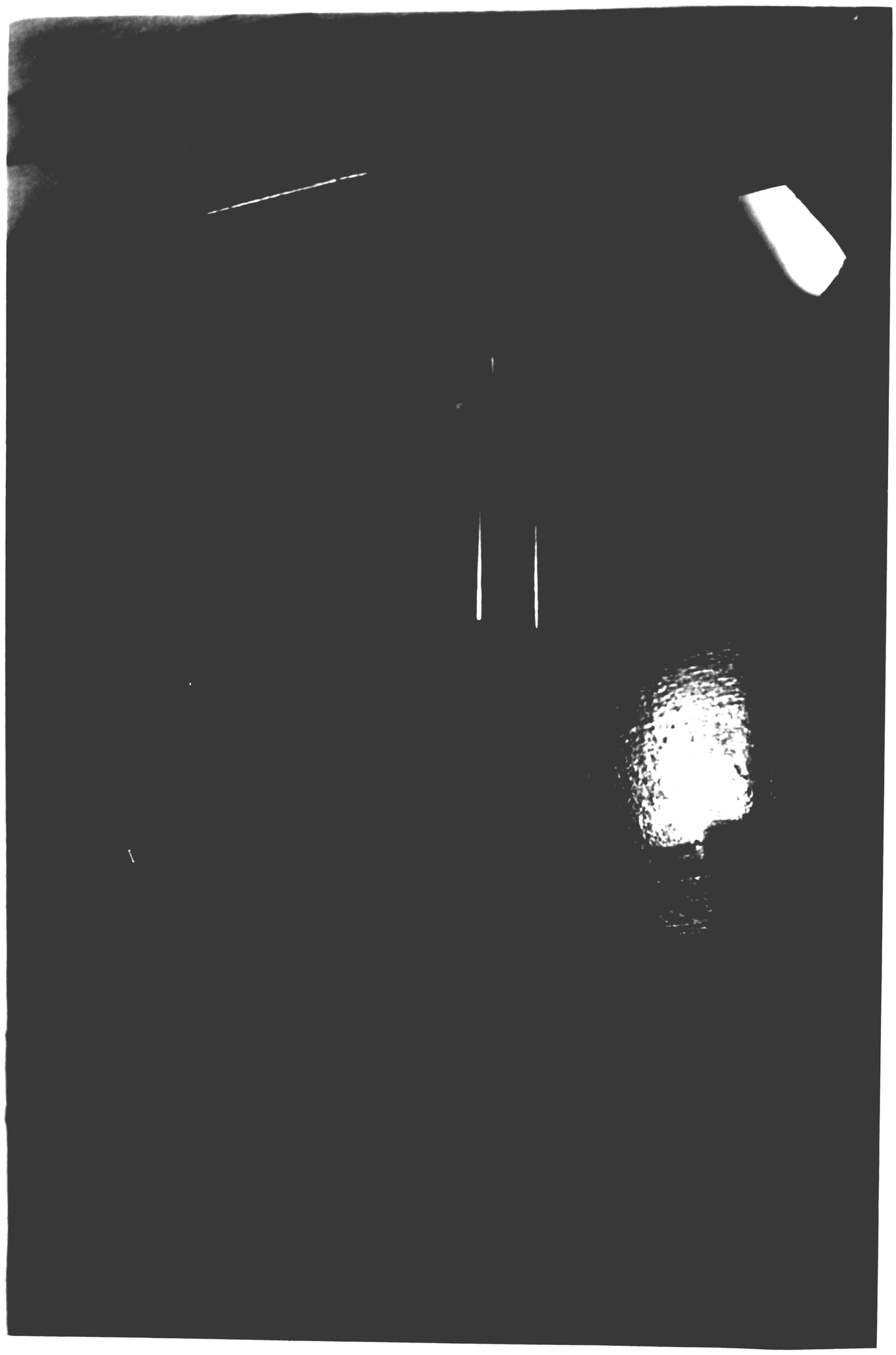

Figure 15.6: Dipping Machine: Support Rod

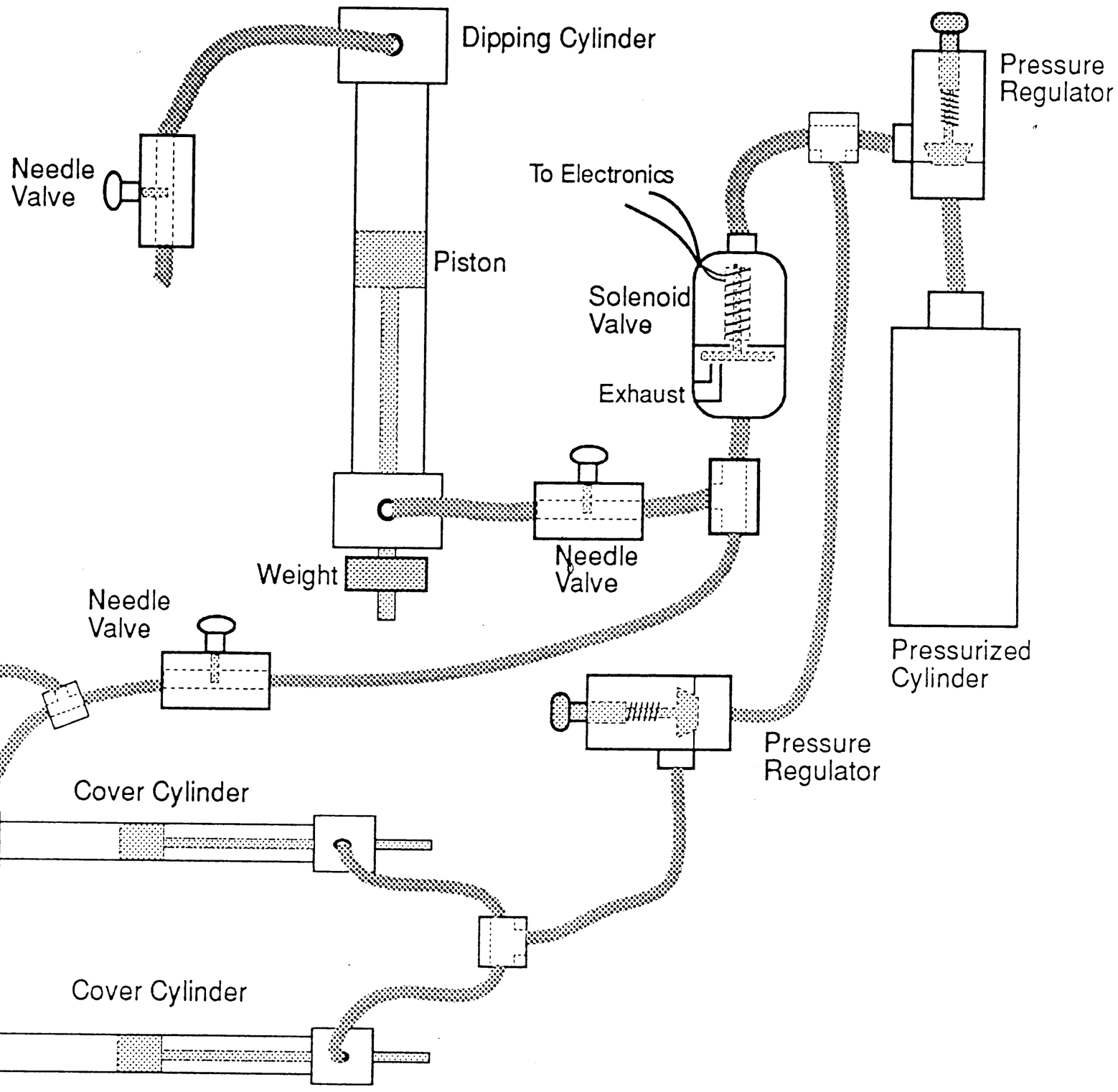

Figure 15.7: Dipping Machine: Schematic of Modified Pneumatics

Figure 15.8: New MBAD

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Appendices

Appendix I
(Chemical Specifications)

Chlorobenzene [C6H5Cl]
Formula Weight: 112.56
Boiling Point: 132℃
Density: 1.107 g/cm^3
Residue: .004%

Cyclohexanone [CH2(CH2)4CO]
Formula Weight: 98.15
Boiling Point: 156℃
Density: 0.947 g/cm^3

Ethyl Acetate [CH3CO2C2H5]
Formula Weight: 88.11
Boiling Point: 76.5-77.5℃
Density: 0.902 g/cm^3

Methylene Chloride [CH2Cl2]
(Dichloromethane)
Formula Weight: 84.93
Boiling Point: 39.8-40℃
Density: 1.325 g/cm^3
Residue: .0004%

Tetrahydrofuran [C4H8O]
(THF)
Formula Weight: 72.11
Boiling Point: 67℃
Density: 0.886 g/cm^3
Residue: .0007%

1,1,1 Trichloroethane [CH3CCl3]
Formula Weight: 133.41
Boiling Point: 74-76℃
Density: 1.338 g/cm^3
Residue: .0002%

Toluene [C6H5CH3]
Formula Weight: 92.14
Boiling Point: 111℃
Density: 0.867 g/cm^3
Residue: .0008%

Appendix II
(Material Specifications)

ELASTOMERIC MATERIALS — THERMOPLASTIC ELASTOMERS

Generic Type						Polyester			Polyester			Polyester			Polyester		
Manufacturer/Supplier						E. I. Dupont			E. I. Dupont			E. I. Dupont			E. I. Dupont		
Resin Subtype or Filler																	
Commercial Name						Hytrel 4055			Hytrel 4056			Hytrel 5526			Hytrel 5555HS		
Features						Exc. low temp flexibility,good flex fatigue resistance			Non-discoloring version of Hytrel 4055			Exc. combination of low and high temp properties			Heat stabilized version of Hytrel 5555		
Uses						Tubing,hose,film, seals gears			Hose covers, molded goods			Auto parts,tires, sports goods,seals			Hose,tubing,wire coating		
	Units of Measure English	Metric	SI	Test ASTM	DIN												
PROCESSING																	
1 Processing Methods						Molding/Extrusion			Molding/Extrusion			Molding			Molding/Extrusion		
2 Inject Stock Melt Temp	°F	°C				355	179		355	179		430	220		430	220	
3 Extrusion Temp	°F	°C				370	187		370	187		435	223		435	223	
4 Linear Mold Shrink	in/in			D955	[53464]	0.003			0.003			0.014			0.014		
5 Melt Flow		g/10min		D1238	[53735]	5			5			18			9		
6 Melting Point	°F	°C				334	167		334	167		412	210		412	210	
7 Density	lb/ft³	g/cm³	Mg/m³	D792	[53479]	73.13	1.170	1.170	73.13	1.170	1.170	75.00	1.200	1.200	75.00	1.200	1.200
8 Form						Pellets/Powder			Pellets/Powder			Pellets/Powder			Pellets/Powder		
MECHANICAL PROPERTIES																	
9 Tensile Str,break	10³lb/in²	10²kg/cm²	MPa	D412	[53504]	3.70	2.60	25.5	3.70	2.60	25.5	5.5	3.87	37.9	5.50	3.87	37.9
10 Tensile Mod 100%	10³lb/in²	10²kg/cm²	MPa	D412	[53504]	1.10	0.77	7.6	1.10	0.77	7.6	2.00	1.41	13.8	2.00	1.41	13.8
11 Tensile Mod 200%	10³lb/in²	10²kg/cm²	MPa	D412	[53504]												
12 Tensile Mod 300%	10³lb/in²	10²kg/cm²	MPa	D412	[53504]												
13 Tensile Set, %				D412	[53504]	18			18			38			38		
14 Elongation %,break				D412	[53504]	450			450			450			450		
15 Flexural Modulus	10³lb/in²	10²kg/cm²	MPa	D790	[53457]	7.00	4.92	48.3	7.00	4.92	48.3	30.00	21.09	206.9	30.00	21.09	206.9
16 Compression Mod 5%	10³lb/in²	10²kg/cm²	MPa	D575													
17 Compression Mod 10%	10³lb/in²	10²kg/cm²	MPa	D575													
18 Compression Mod 25%	10³lb/in²	10²kg/cm²	MPa	D575		1.80	1.27	12.4	1.80	1.27	12.4	3.90	2.74	26.9	3.90	2.74	26.9
19 Compression Set,method B 20-25 hr				D395	[53517]	60[a]			60[a]			56[a]			56[a]		
20 Compression Set,method B 70-75 hr				D395	[53517]												
21 Izod Notch,1/4 inch	ft lb/in	kg cm/cm	J/cm	D256		20.00[b]	108.80	10.68	20.00[b]	108.80	10.68	20.00[b]	108.80	10.68	20.00[b]	108.80	10.68
22 Izod Notch,low temp	ft lb/in	kg cm/cm	J/cm	D758		20.00[b]	108.80	10.68	20.00[b]	108.80	10.68	20.00[b]	108.80	10.68	20.00[b]	108.80	10.68
23 Tensile Impact	ft lb/in²	kg cm/cm²	kJ/m²	1822	[53448]							140	300.16	294.42	140.0	300.16	294.42
24 Tear Strength—Method						Die C			Die C			Die C			Die C		
25 —Value	lb/in	kg/cm	kN/m			700.0	125.3	122.5	700.0	125.3	122.5	900.0	161.1	157.5	900.0	161.1	157.5
26 Abrasion: Taber		mg/1000 cycles loss		D1044		3			3			5			5		
27 NBS, % of Standard						800			800			3540			3540		
28 DIN			mm³		[53516]												
29 Resilience %				D1054		62			62			53			53		
30 Hardness, Shore				D2240	[53505]	D40			D40			D55			D55		
THERMAL PROPERTIES																	
31 Linear Therm Expan	10⁻⁵in/in°F	10⁻⁵cm/cm°C	10⁻⁵mm/mmK	D696	[52328]	11.0	19.80	19.80	11.0	19.80	19.80	10.0	18.00	18.00	10.0	18.00	18.00
32 Vicat Soft Pt	°F	°C		D1525	[53460]	234	112		234	112		356	179		356	179	
33 Brittle Temp	°F	°C		D746		<-94	<-70		<-94	<-70		<-94	<-70		<-94	<-70	
ELECTRICAL PROPERTIES																	
34 Volume Resistivity		Ohm-cm		D257	[53482]	2.3X10¹³			2.3X10¹³			5.6X10¹³			5.6X10¹³		
35 Surface Resistivity		Ohm		D257	[53482]												
36 Insulation Resistance		Ohm		D257	[53482]												
37 Arc Tracking		seconds		D495	[53480]										120		
38 Dielectric Str	V/10⁻³in	kV/mm	MV/m	D149	[53481]	900.0	35.5	35.5	900.0	35.5	35.5	845.0	33.3	33.3	845.0	33.3	33.3
39 Dielectric Constant:50-100 Hz				D150	[53483]												
40 10^3 Hz				D150	[53483]	6.0			6.0			5.0			5.0		
41 10^6 Hz				D150	[53483]												
42 Dissipation Factor:50-100 Hz				D150	[53483]												
43 10^3 Hz				D150	[53483]	0.007			0.007			0.008			0.0008		
44 10^6 Hz				D150	[53483]												
ENVIRONMENTAL PROPERTIES																	
45 Water Absorption %, 24 hrs				D570	[53473]	0.06			0.06			0.5			0.5		
46 Ozone Resistance																	
47 Aging Test Data Available												YES			YES		
48 Notes						[a]Improved by annealing [b]No break			[a]Improved by annealing [b]No break			[a]Improved by annealing [b]No break			[a]Improved by annealing [b]No break		

Metric Units in Red [DIN Test Results]

Appendix II
(Material Specifications Continued)

Estane® Polyurethane Resin Selection Guide

Solution Grade Polymers		Physical Properties							Solubility in: *			
Estane® Polymer No.	Type	Specific Gravity	Shore Hardness ASTM D2240	Tensile Strength ASTM D638 (psi/MPa)	Modulus ASTM D638 100% (psi/MPa)	Modulus ASTM D638 300% (psi/MPa)	Elongation at break ASTM D638 (%)	Glass Transition Temperature (°F/°C)	THF	DMF	MEK	E..
5703	Ester	1.19	70A	4500/31.0	330/2 3	550/3.8	630	– 24/ – 31	S	S	S	S.
5710F1	Ester	1.20	78A	7900/54 4	540/3 7	1950/13 4	420	– 13/ – 25	S	S	Sw	S.
5714F1	Ether	1.11	83A	5500/37.9	700/4 8	1300/9.0	530	– 56/ – 49	S	S	Sw	I
5708F1	Ester	1.20	87A	6100/42.0	800/5 5	2300/15.8	490	– 45/ – 43	S	S	Sw	I
5701F1	Ester	1.21	87A	6400/44.1	850/5 9	2350/16.2	450	– 13/ – 25	S	S	Sw	I
5705F1 5707F1	Ester	1.22	46D	7300/50.3	1400/9.6	5000/34 5	380	– 4/ – 20	S	S	I	I
5715	Ester	1.21	97A/54D	6700/46.2	1450/10 0	–	290	61/16	S	S	S	S

Adhesive Grade Polymers		Physical Properties							Solubility in: *			
Estane® Polymer No.	Type	Specific Gravity	Shore Hardness ASTM D2240	Tensile Strength ASTM D638 (psi/MPa)	Modulus ASTM D638 100% (psi/MPa)	Modulus ASTM D638 300% (psi/MPa)	Elongation at break ASTM D638 (%)	Heat Activation Temperature (°F/°C)	THF	DMF	MEK	E..
5720	Ester	–	90A	1350/9 3	406/2.8	–	500	–	S	S	S	S
5712	Ester	1.20	40D	5400/37.2	850/5.9	1300/9.0	600	130/54	S	S	S	S
5713	Ester	1.20	40D	5500/37.9	680/4.7	1300/9.0	560	130/54	S	S	Sw	S.
5716	Ester	1.20	40D	5900/40.7	640/4.4	1080/7.4	620	130/54	S	S	S	S
5730	Ester	1.20	40D	5700/39.3	730/5.0	1230/8.5	570	130/54	S	S	S	S

Appendix II
(Material Specifications Continued)

Viscosity Specifications† MPa.sec. or cP	Characteristics	Suggested Applications
180-300(D)	Readily soluble, high adhesion, compatible with additives and polymers, talc dusted	Shoe construction adhesives, commercial adhesive systems, fabric lamination, magnetic tape, and sheet adhesives.
400-800(A)	Soft, tough, makes very flexible film with exceptional "hand." Good chemical resistance. Calcium stearate dusted	Fabric coating by direct and transfer methods, commercial coating systems, magnetic tape.
800-1200(A)	Excellent resistance to hydrolysis and fungus attack, exceptional low temperature flexibility, good resistance to chemicals and abrasion. Limited compatibility with other polymers. Calcium stearate dusted.	Fabric coating, wire jackets, tarpaulins.
420-780(B)	Best low temperature flexibility of the polyester based polyurethanes. Calcium stearate dusted.	Coated fabrics top- and tiecoat. Coagulation method of making synthetic suede. Magnetic tape and discs.
400-600(A)	Excellent flexibility, resistance to chemicals and abrasion. Compatible with many additives and other polymers.	Magnetic tape, coated fabrics, adhesive blending polymer.
400-800(A)	Most resistant to chemicals, abrasion and tearing. Highest tensile strength, excellent low temperature flexibility. 5705 is talc dusted; 5707 is calcium stearate dusted.	Magnetic tape, outerwear, leather finishes by direct coating. Gloss and matte leather finish outerwear by transfer coating for coats, boots, purses and luggage. Free film casting, lacquers printing inks
100-200(C)	Readily soluble in MEK. Produces hard, flexible, abrasion resistant coatings. Calcium stearate dusted.	Binders; leather dressing, commercial coatings, paper and foil coatings, spray lacquers for the finishing of leather-like materials.

Viscosity Specifications† MPa.sec. or cP	Characteristics	Suggested Applications
2800-4200(C)	A fast crystallizing, quick-grab adhesive polymer, highly soluble in ketones and ethyl acetate. High temperature resistance after cross-linking with polyisocyanates.	High speed assembly of footwear.
2100-3800(C)	Open tack adhesive series. Highly crystalline. Dries to a non-tacky film. Tack is easily restored by heat or solvent treatment. High strength, flexible bonds	High speed assembly of footwear, multi-material laminates, heat activated "open tack" adhesives in sheet and tape form.
800-1300(A)	Resistant to plasticizers and other chemicals. Talc dusted 5712 maintains good bond strength at approximately 60°C, 5716 at approximately 71°C, and 5713 at 82°C or higher.	
3000-5000(C)		
3000-6000(C)		

ESTANE® thermoplastic polyurethanes occupy a unique position, bridging the gap between rubbery elastomers and rigid plastics. ESTANE® polymers include both aromatic polyester- and polyether-based urethanes. Polyester-based urethanes are strong and resistant to chemicals, while polyether-based materials are exceptionally resistant to both hydrolysis and fungus attack. Because of the exceptional compatibility of ESTANE® polymers with each other and with a wide variety of other polymers, they may be readily compounded to obtain special properties. Polyether-based urethanes are not compatible with polyester-based urethanes.

ESTANE® polymers are available in granular form – ready to be dissolved in appropriate solvent systems, or further compounded. The user can select from these polymers on the basis of final properties, ease of solubility, and application required for his product.

ESTANE® polymers are used for a large variety of applications, such as coated fabrics (transfer coating, direct coating, coagulation process), adhesives (one and two component types), tapes (binders for magnetic pigments), and spray lacquers.

Product types are listed in order of increasing hardness. More specific information is available on request.

* **Solubility:** 16 hours mixing in solvent solids: 20 %

Definitions of Abbreviations:

E.A.: Ethel Acetate.
S : Soluble.
Sw : Swelling.
I : Insoluble.

† **Viscosities:**

A – 15 % solids in THF, Brookfield RVF, No. 2 Spindle, 20 rpm at 22.2 ± 1.1 °C
B – 15 % solids in DMF, Brookfield RVF, No. 2 Spindle, 20 rpm at 22.2 ± 1.1 °C
C – 20 % solids in MEK, Brookfield RVF, No. 4 Spindle, 20 rpm at 22.2 ± 1.1 °C
D – 15 % solids in MEK, Brookfield RVF, No. 2 Spindle, 20 rpm at 22.2 ± 1.1 °C

Appendix II
(Material Specifications Continued)

Silicone Application By Process Technique

Recommended Product Application	Calendaring	Extruding	Injection Molding	Transfer Molding	Compression Molding	Adhesion	Encapsulants	Mold-Making	Inflation Devices	Casting
Implant Grade										
MDX4-4515	■	■		■	■					
MDX4-4516	■	■		■	■					
Q7-2245[2]										■
Medical Grade										
MDX4-4210					■		■	■		
Q7-4535	■	■		■	■					
Q7-4550	■	■		■	■					
Q7-4565	■	■		■	■					
Q7-4650	■	■		■	■					
Q7-4665	■	■		■	■					
Q7-4720					■			■		
Q7-4735	■			■	■					
Q7-4750	■	■		■	■					
Q7-4765	■	■		■	■					
Q7-4780	■	■		■	■					
Q7-4840		■								■
Q7-4850		■								■
Q7-4865		■								
Q7-2213										■
355						■				■
Adhesive A						■	■			■
Q7-2218[2]							■			
Q7-2630*										■
Clean Grade										
Q7-2174	■			■	■					
Q7-4035	■			■	■					
Q7-4055	■			■	■					
Commercial Grade										
595HC		■								■
598		■								■
599HC		■								■
GP30	■	■		■	■					
GP50[1]	■	■		■	■					
GP70[1]	■	■		■	■					
GP950[1]	■	■		■	■					
HE-26								■		
HS-50[1]	■	■		■	■					
HS-70[1]	■	■		■	■					
TR-55[1]	■	■		■	■					
NPC-40[1]	■	■		■	■					
NPC-80[1]	■	■		■	■					
HS-30	■			■	■					
TR-70[1]	■	■		■	■					

Appendix II
(Material Specifications Continued)

Silicone Properties

Product	Primary Features	Cure Conditions	Cure System	Typical Properties
BIO-PSA® 355 Medical Grade Pressure Sensitive Adhesive	Pressure sensitive, bio-compatible adhesive.	Non-curing dispersion becomes adhesive as solvent evaporates.	Non-curing dispersion	**As Received:** Solids content 18.5% Specific gravity at 25°C 1.4 Solvent Trichlorotrifluoroethane. **After Drying Thoroughly:** adhesive strength, aluminum to aluminum bond ozs./in. 100
SILASTIC® Medical Adhesive Silicone Type A	One part silicone elastomer useful for bonding silicone rubber to itself or other implantable synthetics. Also useful to cast films or parts from dispersions.	• Requires humid environment (50% RH). • Cure time a function of thickness 7-days—full cure, can be handled after 24 hour cure.	Acetoxy cure produces acetic acid	Specific gravity 1.06 **Typical Elastomer Properties** Durometer, Shore A 29 Tensile, PSI 450 Elongation, % 400 Tear Die B, ppi 30 Adhesion, SILASTIC® Medical Grade Sheeting, ppi 20+
DOW CORNING® Q7-2218 Silicone Gel System[2]	Firm clear gel • Range of cure time and temp. • Controlled firmness. Applications: • Breast enhancers • Electrical potting • Flotation pads	24 hrs. @ 25°C 4 hrs. @ 65°C 1 hr. @ 100°C 15 min. @ 150°C Two part system, 1A:1B ratio	Platinum cure system	**Viscosity of Gel Fluids:** Q7-2218A 425 cs Q7-2218B 400 cs Gel penetration 45 1:1 ratio Pot life @ 25°C 1.5 hrs. Transparent gel
SILASTIC® Q7-2213 Medical Grade Dispersion	• Ready to use, heat curable silicone elastomer dispersion. • Nonflammable solvent. • Can be applied by spraying, brushing or dipping. • One-part system, no mixing needed.	Temp. ‹210°C Time depends on thickness and temp. 5 mil film, 15 min. at 160°C. (320 °F)	Platinum cure system	**Dispersion** Solids, % 13 **Elastomer** Durometer, Shore 00 82 Tensile, Die C, psi 1,300 Elongation, % 700 Tear Die B, ppi 140
DOW CORNING® Q7-2630 Dispersion System*	A room temp. cure, two-component dispersion system that can be diluted with Q7-2650 Fluid. Can be applied as a coating by dipping, spraying, or brushing.	When catalyzed with Q7-2640 Catalyst for 30 min. @ 25° ± 5°C at 10-50% relative humidity. Optimum cure in 7 days. Can be handled after 16 hour cure.	Acetoxy cure system	**Dispersion** Q7-2630 solids 10% Viscosity, cp 190 **Cured Elastomer** Durometer, Shore 00 70 Tensile, psi 800 Elongation, % 900 Modulus at 200%, psi 50

Appendix II
(Material Specifications Continued)

Elastomer	Description	Catalyst	Conditions	Typical Properties: Durometer, Shore A	Tensile	Elongation	Tear Die B	Specific Gravity
Implant Grade MDX4-4515	1-part high consistency catalyzed silicone elastomer.	Peroxide	Press cure 5 min. at 116°C. Oven cure 2 hrs. at 249°C.	52	1,350	450	80[3]	1.15
MDX4-4516	1-part high consistency catalyzed silicone elastomer.	Peroxide	Press cure 5 min. at 116°C. Oven cure 2 hrs. at 249°C.	72	1,175	370	70[3]	1.21
SILASTIC® Q7-2245[2] Medical Grade	A 3-part platinum cure system suitable for dispersion.	Platinum	Q7-2245 (100 parts of A, 70 parts of B, 32 parts of C) cured 10 minutes at 171°C and post cured 2 hrs. at 149°C.	41	1,300	700	140	1.15
Medical Grade Q7-4535	Uncatalyzed enhanced tear resistant silicone elastomer.	Peroxide	Press cured 5 mins. at 116°C and post cured 2 hours at 177°C with CADOX-TS50 at 1 part per 100 parts base.	33	1,200	1,015	160	1.10
MDX4-4210	A 2-part room temp. curing silicone elastomer.	Platinum	Cured one hour at 150°C.	>25	>550	>350	~50	1.10
Q7-4550	Uncatalyzed enhanced tear resistant silicone elastomer.	Peroxide	Press cured 5 mins. at 116°C and post cured two hours at 177°C with CADOX-TS50 at 1 part per 100 parts base.	51	1,375	600	170	1.14
Q7-4565	Uncatalyzed enhanced tear resistant silicone elastomer.	Peroxide	Press cured 5 mins. at 116°C and post cured two hours at 177°C with CADOX-TS50 at 1 part per 100 parts base.	66	1,000	550	210	1.20
Q7-4650	Catalyzed enhanced tear resistant silicone elastomer.	Peroxide	Press cure 5 mins. at 116°C and post cured two hours at 177°C.	51	1,375	600	170	1.14
Q7-4665	Catalyzed enhanced tear resistant silicone elastomer.	Peroxide	Press cure 5 mins. at 116°C and post cured two hours at 177°C.	66	1,000	550	210	1.20
Q7-4720	Two part catalyzed enhanced tear resistant silicone elastomer.	Platinum	Press cure 10 mins. at 116°C. Equilibrated 16 hours at room temperature.	23	1,200	1,100	150	1.10
Q7-4735	Two part catalyzed enhanced tear resistant silicone elastomer.	Platinum	Press cure 10 mins. at 116°C. Equilibrated 16 hours at room temperature.	35	1,050	1,200	200	1.10
Q7-4750	Two part catalyzed enhanced tear resistant silicone elastomer.	Platinum	Press cure 10 mins. at 116°C. Equilibrated 16 hours at room temperature.	50	1,300	900	230	1.14
Q7-4765	Two part catalyzed enhanced tear resistant silicone elastomer.	Platinum	Press cure 10 mins. at 116°C. Equilibrated 16 hours at room temperature.	63	925	900	220	1.20
Q7-4780	Two part catalyzed enhanced tear resistant silicone elastomer.	Platinum	Press cure 10 mins. at 116°C. Equilibrated 16 hours at room temperature.	78	850	600	190	1.22
Q7-4840	Two part catalyzed liquid silicone rubber.	Platinum	Press cure 5 mins. at 150°C.	40	950	425	150	1.12
Q7-4850	Two part catalyzed liquid silicone rubber.	Platinum	Press cure 5 mins. at 150°C.	50	1,350	550	225	1.14
Q7-4865	Two part catalyzed liquid silicone rubber.	Platinum	Press cure 6 mins. at 150°C.	65	1,200	500	275	1.14

Appendix II
(Material Specifications Continued)

Silastic® Elastomer Comparison Guide

	Implant Grade	Medical Grade	Clean Grade	Commercial Grade
Bio-Testing				
Two-year implant data available	■			
Meet or exceed USP Class VI Plastics Test	■	■		
Pyrogen	■	■		
Skin sensitization	■	■		
Tissue cell culture	■	■		
90-day implant with histopathology on all major organs	■			
Quality Controls				
Lot testing for 28 trace metals*	■	■	■	
FDA Registered plant using GMPs	■	■	■	
Lot quality control	■	■	■	
Lot traceability	■	■	■	
Product certification	■	■	■	
Physical properties audited on a regular basis	■	■	■	
Four-year sample retention	■	■	■	
90-day sample retention	■	■	■	■
All multi-component materials are lot matched	■	■	■	■
Packaging				
Units separately wrapped, sealed and labeled	■	■	■	
Each 25 lb. unit wrapped separately	■	■	■	■
Strained through 200 mesh	■	■	■	
50 lb. boxes strained through 120 mesh	■	■	■	■
1,000 lb. boxes screened through 120 mesh	■	■	■	■
Technical Service & Samples				
Free samples	■	■	■	■
Test results on request	■	■	■	■

*Gels 355, 2630, 2640 and 2650 do not have heavy metals testing.

Appendix III
(Formulations of Polyurethanes)

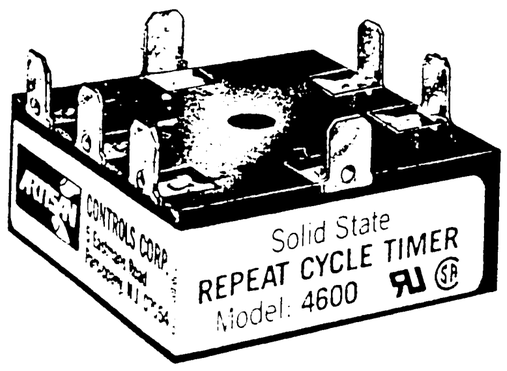
Chemicals: THF, Cyclohexanone (see Appendix I)
Estanes: No. 5701, 5703, & 5707- from BFGoodrich (see Appendix II)

Outer Shell Material:	46 ml 5701 69 ml 5707 720 ml THF 180 ml Cyclohexanone
Bladder* Material:	23 ml 5701 34 ml 5707 58 ml 5703 720 ml THF 180 ml Cyclohexanone

* More experiments should be done with this formulation.

Appendix IV
(Timer Specifications)

4600 repeat cycle timer



- Digital Timing Circuitry
- 1 Ampere Output
- Fixed and Adjustable Times
- U/L Recognized
- CSA Certified

The model 4600 is a repeat cycle timer which can be used to replace existing electromechanical cycle timers. It is used for applications in which the load circuit is energized for a period of time then de-energized for a period of time. This cycle is repeated for as long as operating voltage is applied to the timer. The model 4600 operates with either AC or DC voltages and can control loads of up to 1 ampere. It is available with either fixed or adjustable timing.

SPECIFICATIONS

OPERATING VOLTAGE: 12, 24, 48 Volts DC, 24, 48, 120, 240 Volts AC. 50/60 Hz for AC voltages. Other voltages available upon request.

OPERATING VOLTAGE TOLERANCE: ±20%.

TIMING MODE: Repeat Cycle.

TIMING RANGE: Fixed units — Cycle time, 200 milliseconds to 24 hours.
— Energized time, 100 milliseconds to 24 hours.
Adjustable units — Cycle time, 5 ranges from 200 milliseconds to 16,000 seconds.
— Energized time, 5 ranges from 100 milliseconds to 8,000 seconds.

TIMING ADJUSTMENT: Fixed units — None, times fixed internally at factory.
Adjustable units — resistor or potentiometer connected across proper terminals, rating of ¼W or better.

TIMING TOLERANCE: Fixed units — Specified as dash nos.
Adjustable units - minimum time -15%, +0%. maximum time -0%, +15%.

TIMING VARIATION: ±15% at any combination of operating voltage and temperature.

TIMING REPEATABILITY: ±1% at stabilized operating voltage and temperature.

OUTPUT RATING: 10 milliamperes to 1 Ampere inductive. Inrush currents to 25 Amperes for 8 milliseconds.

OUTPUT VOLTAGE DROP, "ON" STATE: 4 Volts maximum, 3 Volts nominal.

OUTPUT LEAKAGE CURRENT: "OFF" STATE: 3 milliamperes maximum.

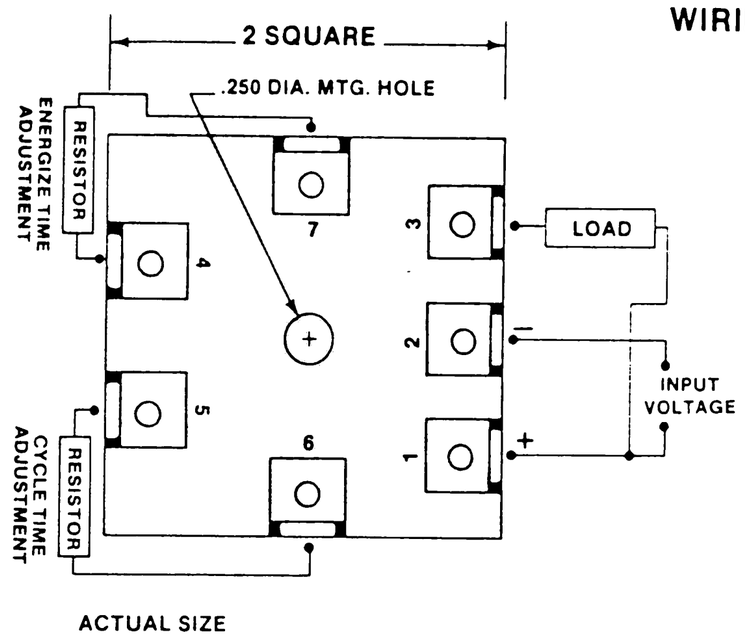
DIELECTRIC 1500 VRMS from all terminals to case.

OPERATING TEMPERATURE: -20°C to +85°C.

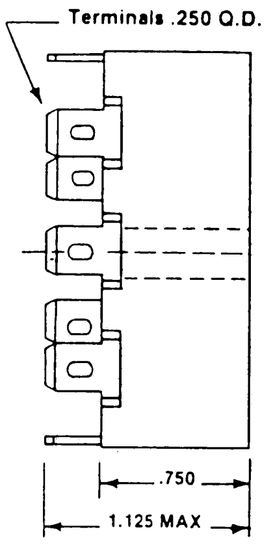
Controls Corporation • P.O. Box 233 • 5 Eastmans Road, Suite 100 • Parsippany, N.J. 07054 • (201) 428-1770

Appendix IV
(Timer Specifications Continued)

WIRING AND DIMENSION DIAGRAM

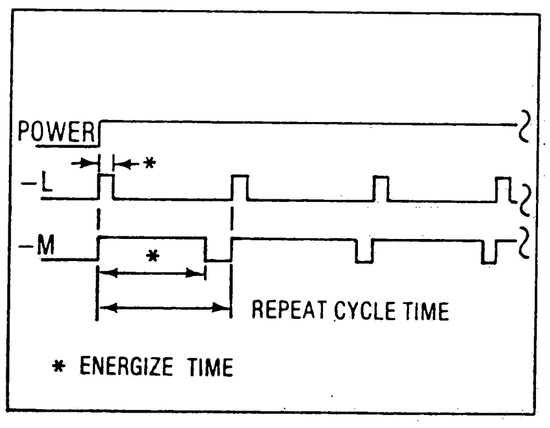


ACTUAL SIZE



APPLICABLE TO 4600 AND 4610 —

TIMING DIAGRAM



ENERGIZED TIME RANGE CODES

- L A (-L) will provide a maximum energized time of 50% of the set repeat cycle time, regardless of the energized time resistor or potentiometer setting.

- M The minimum energized time is automatically 50% of the set repeat cycle time. If additional time is needed, connect a resistor or potentiometer across terminals 4 & 7 (See timing range chart)

Example: 4600A-6-3-2-L/M

Using a (-3) repeat cycle time range and a (-2) energize time range, set the repeat cycle time for 200 seconds by connecting a 1 Meg ohm resistor across terminal 5 & 6.

- L With the repeat cycle time set at 200 seconds, the energized time is adjustable from 1 second to a maximum of 100 seconds, which is 50% of the repeat cycle time.

  Timing adjustment of a -2 timing range:

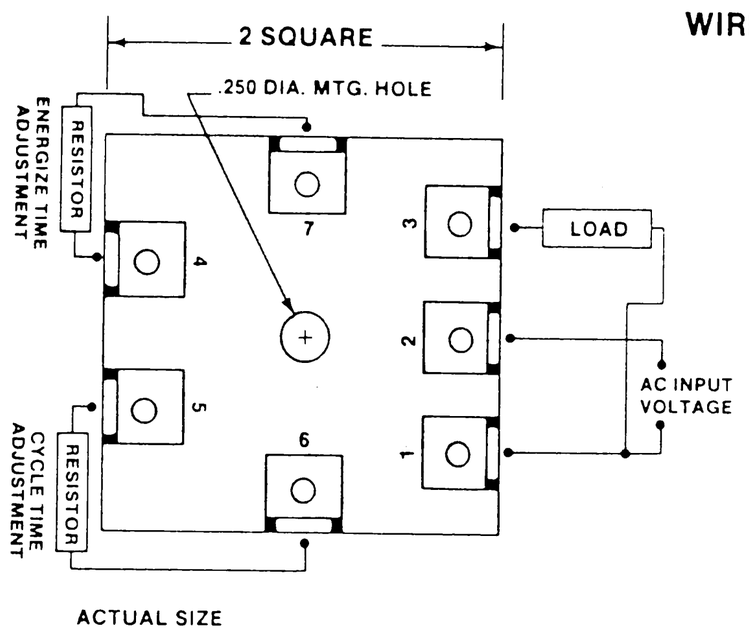
  1 Meg = 1 - 30 seconds energized time
  3 Meg = 1 - 90 seconds energized time
  5 Meg = will give no more than 100 seconds energized time

- M The load is automatically energized for the first 100 seconds, which is 50% of the repeat cycle time. Connecting a 3 Meg ohm potentiometer across terminals 4 & 7 will add up to 90 seconds to this time. The load will be on for 100 - 190 seconds out of the 200 second cycle. A 5 Meg ohm potentiometer will allow the load to be on for the entire cycle.

Continued on page 53

Appendix IV
(Timer Specifications Continued)

WIRING AND DIMENSION DIAGRAM



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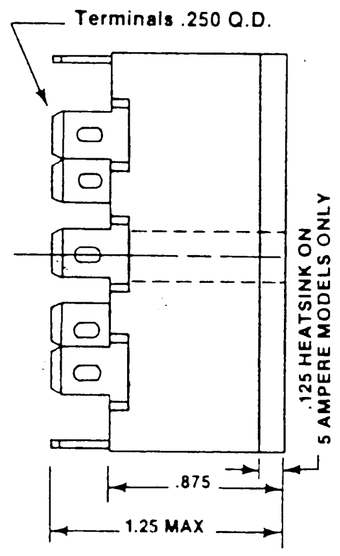


APPLICABLE TO 4600 AND 4610 —

REPEAT CYCLE TIME CHART

EXTERNAL RESISTANCE (OHMS)	DASH NO.				
	-1	-2	-3	-4	-5
0	0.2	2	4	20	60
1 MEG	8	60	200	1.000	1.800
3 MEG	24	180	600	3.000	5.400
5 MEG	40	300	1.000	5.000	9.000
10 MEG	60	600	2.000	10.000	16.000

NOTE: Above timing ranges are in seconds and are supplied to a tolerance of 10%.

ENERGIZE TIME CHART

EXTERNAL RESISTANCE (OHMS)	DASH NO.				
	-1	-2	-3	-4	-5
0	0.1	1	2	10	30
1 MEG	4	30	100	500	900
3 MEG	12	90	300	1500	2700
5 MEG	20	150	500	2500	4500
10 MEG	30	300	1000	4500	8000

NOTE: TIME RANGES ARE IN SECONDS

ORDERING INFORMATION

SERIES	ADJUSTMENT	4600 OPERATING VOLTAGE	4610 OPERATING VOLTAGE	REPEAT CYCLE TIME	R.C.T. TOLERANCE	ENERGIZE TIME	E. TIME TOLERANCE	E. TIME RANGE CODE
4600	F-Fixed	-1 12VDC		-1 0.2-60	-A 2% [1]	-1 0.1-30	-A 2% [1]	-L Less than
4610	A-Adjustable	-2 24VDC		-2 2-600	-B 5% [2]	-2 1-300	-B 5% [2]	50% of R.C.T
		-3 48VDC		-3 4-2000	-C 10%	-3 2-1000	-C 10%	-M More than
		-4 24VAC	-4 24VAC	-4 20-9000	-D 20%	-4 10-4500	-D 20%	50% of R.C.T
		-5 48VAC	-5 48VAC	-5 60-16000		-5 30-8000		
		-6 115VAC	-6 115VAC		FIXED		FIXED	ADJUSTABLE
		-7 240VAC	-7 240VAC	FIXED UNITS	UNITS	FIXED UNITS	UNITS	UNITS ONLY
			AC	SPECIFY IN	ONLY	SPECIFY IN	ONLY	
			ONLY	SECONDS		SECONDS		

[1] = For cycle times under 500 seconds, energize times under 250 seconds only.
[2] = For cycle times under 1200 seconds, energized times under 600 seconds only

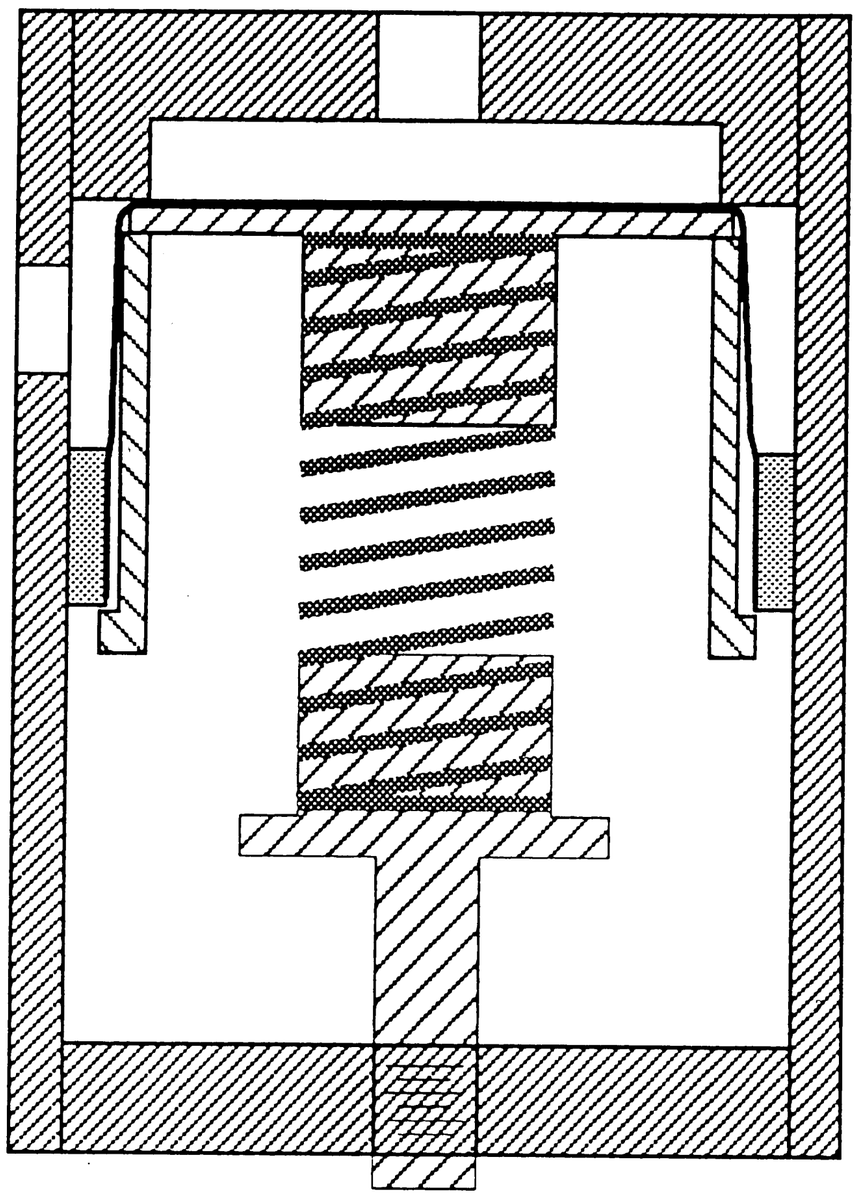
4600A-6-3-2-L

This is a model 4600 with adjustable timing (A), operating from 115 Volts AC (-6), with a repeat cycle time adjustable from 4 - 2000 seconds (-3), an energized time range of 1 - 300 seconds (-2), and with a maximum energized time of 50% of the set cycle time (-L).

4610F-6-3600-B-180-C

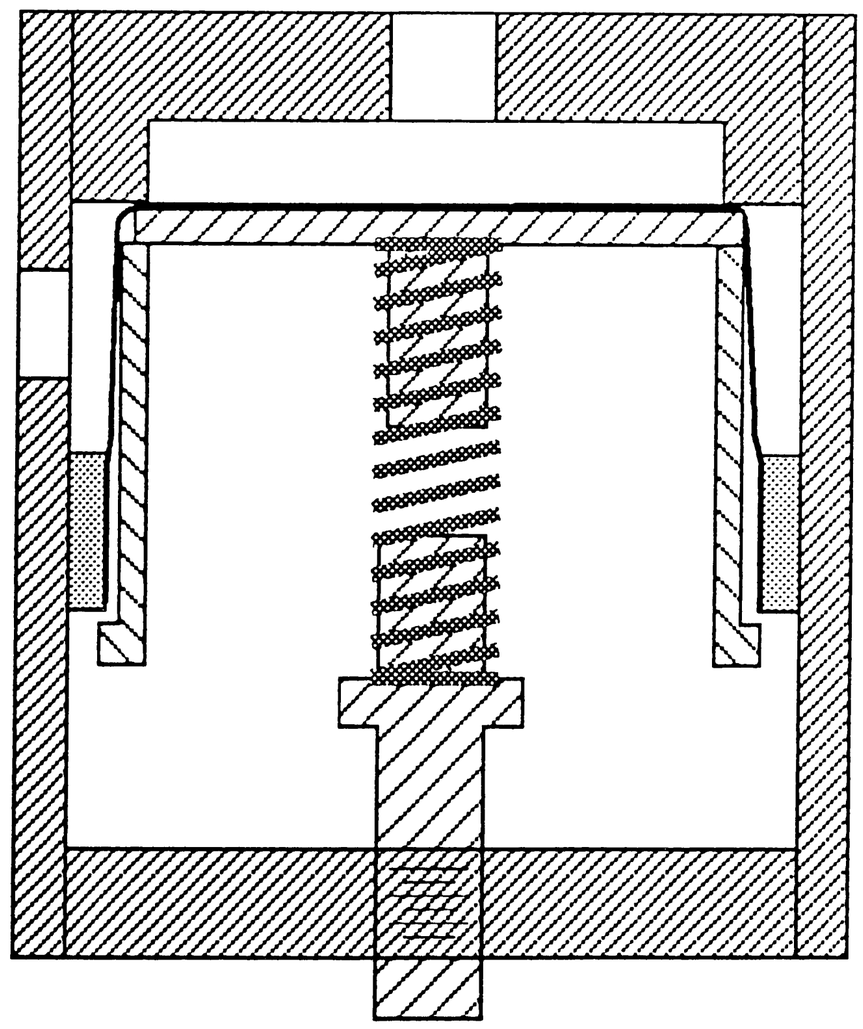
This is a model 4610 with fixed timing (F), operating from 115 Volts AC (-6), with a repeat cycle time of 3600 seconds (-3600) and a repeat cycle time tolerance of 5% (-B), an energized time of 180 seconds (-180) and a energized time tolerance of 10% (-C). This unit will energize a 120 VAC load for 180 seconds every 3600 seconds. (3 minutes every hour).

Appendix V
(Pressure Cylinder Specifications)



LEFT
Specs:
3 1/2" ID Cylinder
4" OD Cylinder
~5.25" long
1.225 x 3.5" Spring
R=10.24 lb/in
1.13 x 3.2" Diaphragm
7.52 in^2 EPA

RIGHT
Specs:
3 1/2" ID Cylinder
4" OD Cylinder
~4.35" long
.6 x 2.25" Spring
R=4.33 lb/in
1.13 x 3.2" Diaphragm
7.52 in^2 EPA



Appendix VI
(List of Products and Suppliers)

Pig Hearts
Baringer Bros.
Richlandtown, PA
(215) 536-4337
(Butcher (Greg) supplies pig hearts.)

Silicone II Rubber Sealant
General Electric Co.
King of Prussia, PA
(215) 337-4430
(Available from any hardware store.)

Silastic Medical Adhesive Type A
Silastic Q7-2213
Dow Corning Medical
Parsippany, NJ
(201) 691-1414

Acrylic Plastic
United States Plastic Corp.
Lima, Ohio
(800) 537-9724

Freon Cylinders (TR70230-50)
VWR Scientific
Philadelphia, PA
(800) 257-8407

Air Cylinders (SDR-05 & UDR-12)
Minimatic Fittings
Clippard Instrument Laboratory, Inc.
Distributed by: Airline Hydraulics
Bethlehem, PA
(215) 758-9400

Timers
A. A. Electric
Harrisburg, PA
(800) 237-8274

Hytrel ®
E.I. Dupont De Nemours & Co.
Wilmington, DE
(800) 341-4004

Intra-aortic Balloon Pumps
Mansfield Scientific Inc.
Mansfield, MA
(508) 339-4112
(Contact: Tom Richardson)

Estane Polyurethanes
BFGoodrich
Speciality Polymers & Chemicals Div.
Cleveland, Ohio
(800) 543-2912
(Contact: Josephine Stearns)

Compression Springs
Associated Spring-Raymond
Bristol, CT
(203) 582-1358

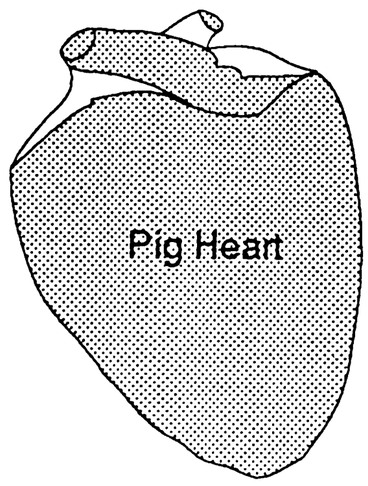
Hydropolymer Coatings
Hydromer Inc.
Whitehouse, NJ
(201) 543-9034

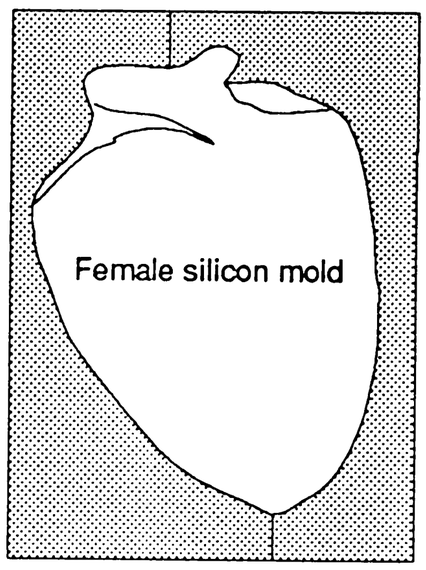
Stepless Ear Clamps
Oetiker, Inc.
Livingston, NJ
(201) 992-1920
(Contact: Chris Grieshaber)

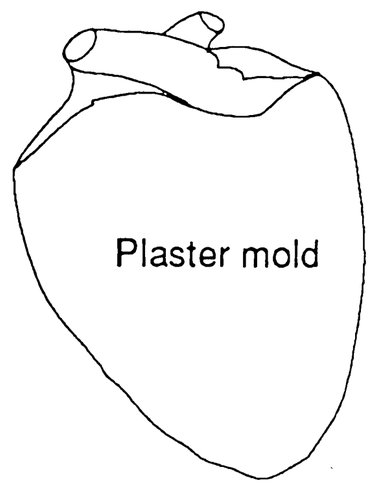
Suppliers
C & H Sales Co.
Pasadena, CA
(800) 325-9465

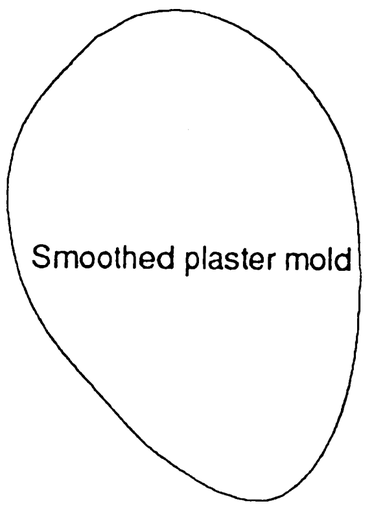
McMaster -Carr Supply Co.
New Brunswick, NJ
(201) 329-3200

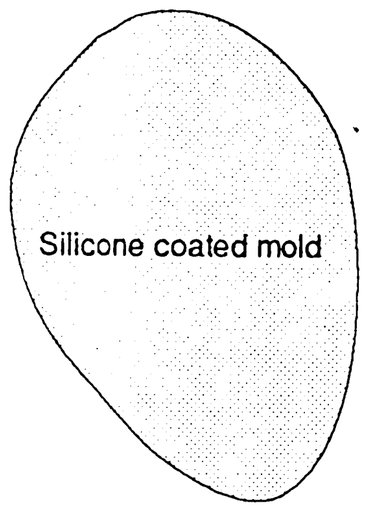
Appendix VII
(Total Fabrication Process)

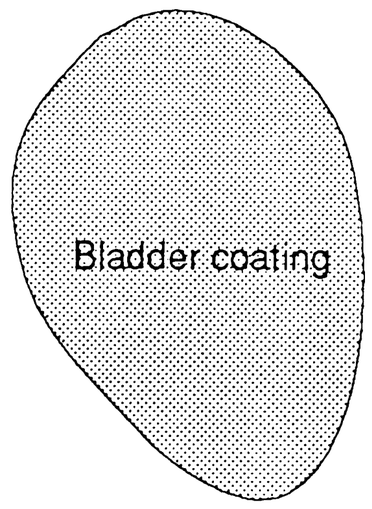


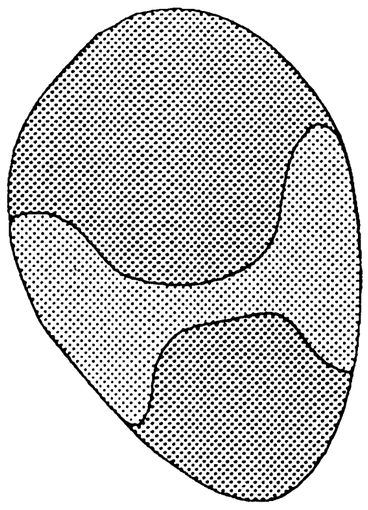




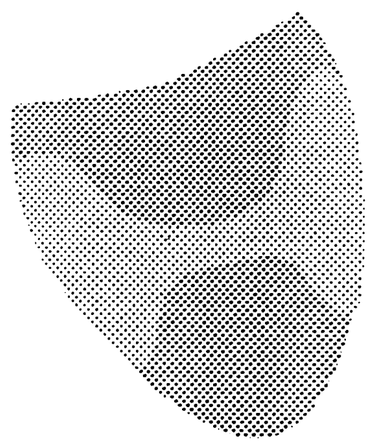




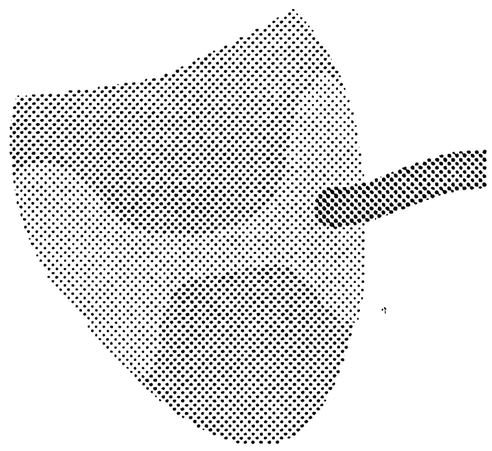




Gelatin separating
bladder from outer shell



MBAD removed from mold



Finished MBAD with
tubing attached

Appendix VIII
(Supplementary Figures)

Dipping Machine Producing New MBAD

Appendix VIII
(Supplementary Figures)

Outer Shell of MBAD Being Dipped

Appendix VIII
(Supplementary Figures)

Completed MBAD With Vacuum Attachment at Apex

Appendix VIII
(Supplementary Figures)

MBAD Next to Intra-aortic Balloon Pump

Appendix VIII
(Supplementary Figures)

MBAD: Simulation of Relaxed Heart

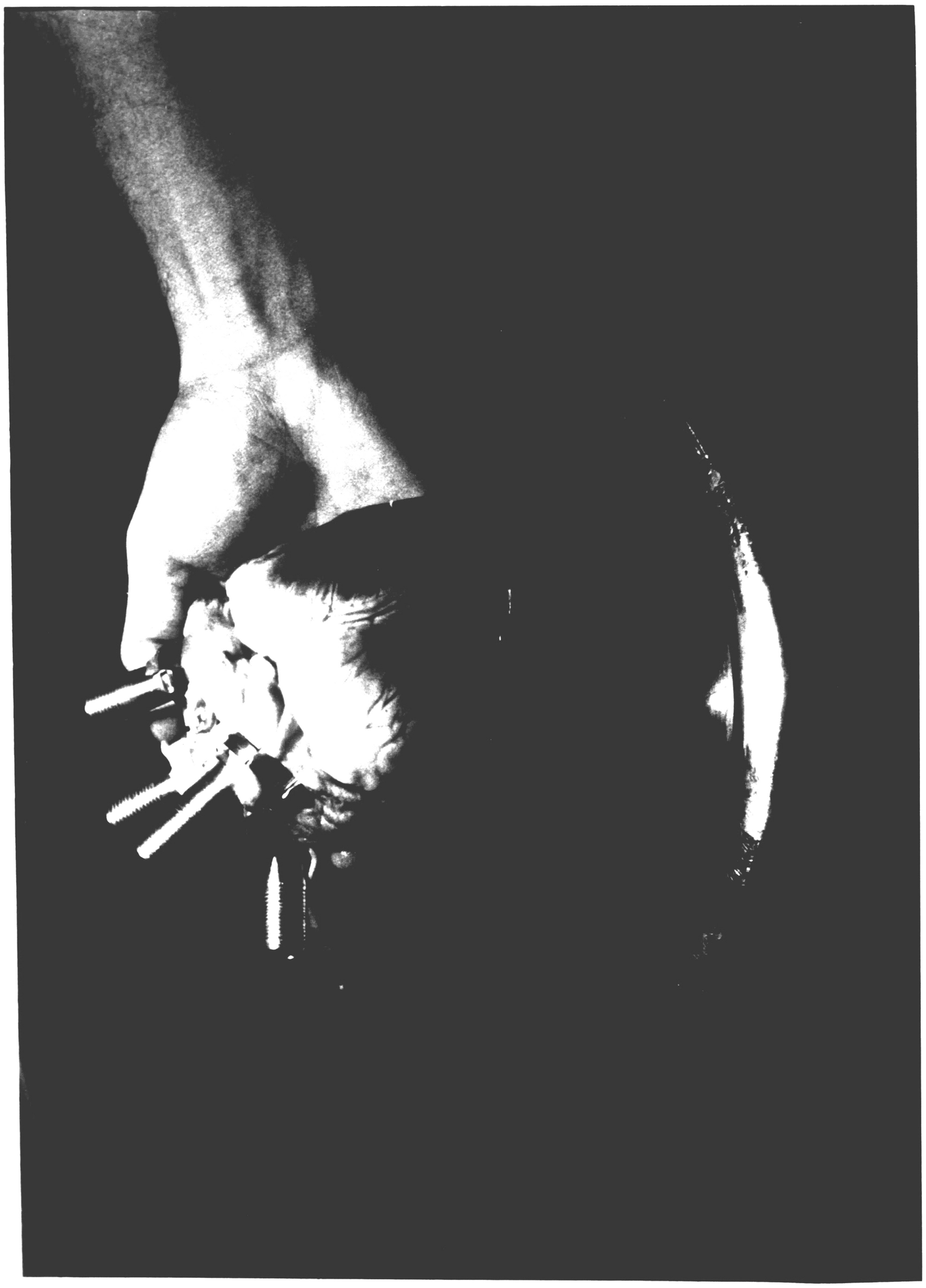
Appendix VIII
(Supplementary Figures)

MBAD: Simulation of Contracted Heart

Appendix VIII
(Supplementary Figures)

Pig Heart As Obtained From Butcher

Appendix VIII
(Supplementary Figures)



Pig Heart With Fittings Attached

Appendix VIII
(Supplementary Figures)

MBAD Over Pig Heart

Appendix VIII
(Supplementary Figures)

Physiological Test Stand With Pig Heart Attached

Appendix VIII
(Supplementary Figures)

Entire Test Setup

Vita

The author, born near Philadelphia, Pennsylvania on July 31, 1967, is the son of Dr. Albert Armour and Mrs. Andrea Armour.

During the years, 1978 through 1983, he lived with his parents and brother in Belgium, near Brussels and attended the International School of Brussels (I.S.B.). Upon returning to the Philadelphia area in the year, 1983, he attended Friends' Central School. In 1985, he graduated from Friends' and attended Lafayette College until graduating in 1989 with a Bachelor of Science degree in mechanical engineering. While attending Lafayette, three summers were spent at E.I. Dupont De Nemours & Co. as a research engineer. After graduating from Lafayette, he pursued a Master of Science degree in mechanical engineering at Lehigh University under a research assistantship.