TRANSPLANT ORGAN PRESERVATION COOLER

by

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(ABSTRACT)

A method for preserving transplant organs for extended periods of time has been developed in the transplant organ preservation cooler. The preservation cooler enhances organ viability by maintaining a temperature controlled organ bath and pumping perfusate through the transplant organ.

The emphasis on the transplant organ preservation cooler is to provide a simple and portable system which will be powered by boiled off oxygen from a liquid oxygen source. The design of the preservation cooler pump and temperature control system are presented. Results of tests proving the successful operation of the preservation cooler prototype are also presented.

Acknowledgements

I would like to thank Dr. Leon J. Arp for all his patience and insight on this project. I would also like to thank my family for all their encouragement during my studies. Additionally, I would like to thank my friends for their continual support: Jackie Trischman, Maureen Ventrice, Eric Albright, Emily Scott, Jeff Stastny, Pat Jessee, Allen Clem, Linda Blevins and Dave Hendricks.

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1.0 Introduction

In organ transplantation, preservation is used to maintain organ viability while the organ is being transported, and to allow time for the recipient to be tested and prepared for transplantation. Current methods of organ preservation include cold storage in ice, normothermic perfusion with a preservation solution, autoperfusion using normothermic blood, and hypothermic perfusion using a preservation solution. In clinical use, cold storage is favored due to the simplicity of the method. Maximum preservation time currently being achieved is approximately five hours [1], depending on the organ.

The goal of the transplant organ preservation cooler is to provide a hypothermic perfusion device which will maintain healthy organ tissue for over 24 hours. The main aim in the development of the cooler is to provide a simple and portable system which is cooled and powered by liquid oxygen. Oxygen gas is also used to oxygenate the perfusion fluid to enhance organ viability.

The transplant organ preservation cooler is a self-contained, portable vessel in which transplant organs are maintained at low temperatures (2° - 6° C; 36° - 43° F) while also being perfused. The organ bath is pre-cooled to 2° - 3° C (36° - 37° F) with ice and the temperature of the organ bath is maintained by cooling it with boiled off oxygen. Cool oxygen gas from the Dewars flask is channelled into tubing within the organ bath to maintain temperatures, and the gas exits to power the pump.

The organ is situated in a Ringer's lactate solution bath and is surrounded by porous packing to cushion the organ. This same fluid is pumped through the organ at a rate of 10-25 ml/min (0.615 - 1.536 in^3/min) as the perfusate. Fluid flowing through the organ is moved by means of a diaphragm pump. The driving force of this pump is boiled off oxygen which is obtained from the liquid oxygen in the Dewars flask. The pump works at a very low rate (10-25 ml/min; 0.615 - 1.536 in^3/min), adjustable through use of a needle valve.

2.0 Literature Survey

Many researchers have investigated the problem of organ preservation. Several methods of preservation have been attempted, including cold storage, normothermic perfusion, autoperfusion, and hypothermic perfusion. In most cases, preservation time in clinical situations has been limited to 4-6 hours [1,2,3]. Storage time also varies with the type of organ. Preservation of the heart and lungs has typically provided the greatest challenge in organ preservation [1,2,4,5].

Cold storage, in which the organ is packed in a cold saline solution (approximately 4° C; 39° F, depending on the organ) and then packed in ice [2], has been the favored clinical preservation method due to its simplicity [2,6,7]. Variations in the solution in which the organ is packed has shown some improvement on preservation time experimentally [4,6,8,9,10], although clinical trials have yet to be attempted.

Normothermic perfusion consists of body temperature (37° C, 99° F) preservation solution being pumped through the transplant organ. This method of organ storage requires use of a cumbersome perfusion device and a qualified perfusion technician [6]. In a study of kidney preservation using normothermic perfusion, storage times of an average of 29 hours were achieved [7]. Lack of portability, cost, and complexity of use of the perfusion devices remain a barrier against widespread clinical use of normothermic perfusion.

Autoperfusion is used in the preservation of heart-lung combinations and consists of ventilating the lungs and allowing the heart to continue circulation of blood [11]. Temperature of the blood is maintained at body temperature by immersing the heart-lung combination into a temperature controlled bath [2,12]. Preservation times of 4-6 hours have been attained using autoperfusion [12]. Using glucose, insulin and antibiotic support, preservation times of up to 24 hours may be attained using autoperfusion [13].

Hypothermic perfusion preserves organs at low temperatures (6° - 8° C, 43° - 46° F [14]) while also perfusing the organ with a preservation solution. Various devices have been used to perform hypothermic perfusion, including a roller pump using fluid at 4° C (39° F) [1], a roller pump moving Ringer's lactate solution which is cooled with ice water [2], and an air-lift pump in an insulated stainless steel container packed with ice [5,14,15]. Clinical testing of the air-lift pump storage device preserved hearts for 7-17 hours [3].

The air-lift pump uses no mechanical or electrical parts, yet relies on ice in an insulated container to maintain transport temperatures [15]. The air-lift pump works by channelling fluid from a reservoir into a pipe where gas is bubbled in with the fluid. This effectively reduces the specific gravity of the fluid and lifts the fluid to the surface of the pipe [16]. The transplant organ preservation cooler described herein relies on the cooling effects of boiled off oxygen from a liquid oxygen source, as well as the power received from the compressed oxygen, to cool and perfuse the organ. No storage device of this type was mentioned in current literature.

3.0 Materials and Methods

The problem addressed by the transplant organ preservation cooler is the effective, long-term storage of transplant organs for transport. Current equipment used for preservation needs to be improved to assist in attaining longer preservation time and longer transport distances. Maintenance of organ viability for extended periods will allow for tissue typing of donor and recipient and result in greater success in organ transplants.

The goal of the transplant organ preservation cooler is to provide stable preservation in a portable unit. Two criteria were used as a basis for the preservation cooler model. To extend preservation times, hypothermic perfusion of the organ at flow rates of 10-25 ml/min (0.615-1.536 in^3/min) is desired. Also, temperature within the cooler must be maintained within the range of 2° - 6° C (36° - 43° F).

3.1 Power and Control Requirements

The method chosen to power the preservation cooler is to use a Dewars flask containing liquid oxygen on-board the preservation cooler. The oxygen which boils off from the liquid oxygen reservoir exists under pressure and is harnessed to cool the organ bath and to pump the perfusate. Several methods of both pumping the perfusate and controlling the preservation cooler temperature were considered.

Pumping methods considered for moving the perfusate include roller pump, controlled volume pump, and diaphragm pump. In an effort to keep the preservation cooler a simple and portable unit, electrically run pumps requiring power sources were not considered practical. A pneumatically run diaphragm pump, powered with compressed oxygen boiled off from the Dewars flask on-board the preservation cooler, was deemed a practical method of pumping the perfusate.

Temperature detection and control methods considered include thermocouples, thermistors, transistors, bimetallic strips, and an open loop cooling system in which boiled off oxygen is channelled through tubing in the organ bath. Again, methods which did not require electricity, and thus a power source, were favored. As a closed loop option for cooling, the action of the bimetallic strip was chosen to control the opening and closing of a valve which, when open, allows oxygen boiled off from the Dewars flask to be channelled into heat exchanger tubing which enters the organ vessel and cools the organ bath. When the valve is closed, oxygen is channelled out a vent valve. A second option of cooling the organ bath consists of open loop temperature maintenance which functions by running heat exchanger tubing directly from the Dewars flask into the organ bath, with exit gas being used to run the pump.

3.2 Compressed Gas Powered Pump

The compressed gas powered pump used in the transplant organ preservation cooler is intended to be powered by oxygen which boils off from the liquid oxygen in the Dewars flask on-board the preservation cooler. A proportional pressure relief valve on the Dewars flask is set at 150 kPa gage (22 psig), therefore the pump is powered by compressed gas at just below 150 kPa (22 psig). The pump design uses the compressed oxygen to power the pump, then sends expelled oxygen on to be vented to atmosphere.

3.2.1 Pump Apparatus

The preservation cooler pump apparatus consists of a needle valve, two oxygen valves, two cylinders with yoke attached, a lever arm with springs attached, an oxygen source, a diaphragm pump, and stainless steel tubing. Figure 1 shows the pump configuration. Referring to Figure 1, oxygen inlet valve V1 interfaces with the oxygen source via needle valve NV and directs incoming oxygen along the proper path. Oxygen outlet valve V2 either allows depressurization of the diaphragm pump by directing gas exiting from the system to the vent, or blocks the path of the oxygen so that the diaphragm pump may be pressurized.

The needle valve is a commercial valve which is opened or closed by turning a screw on the needle valve shaft. The oxygen valves are made of aluminum, with 10-32 threaded holes for tubing connectors existing in the valve casing. The oxygen valve shafts are grooved to hold size 6 (6.35 mm, 0.2500 in. outside diameter; 3.18 mm, 0.1250 in. inside diameter) rubber o-rings which act as gates to channel the flow of oxygen. The oxygen valve shafts also contain 6-32 threaded holes which face the lever arm and are used to connect the oxygen valve shafts to the lever arm via a threaded shaft. Detail drawings are contained in Appendix A.

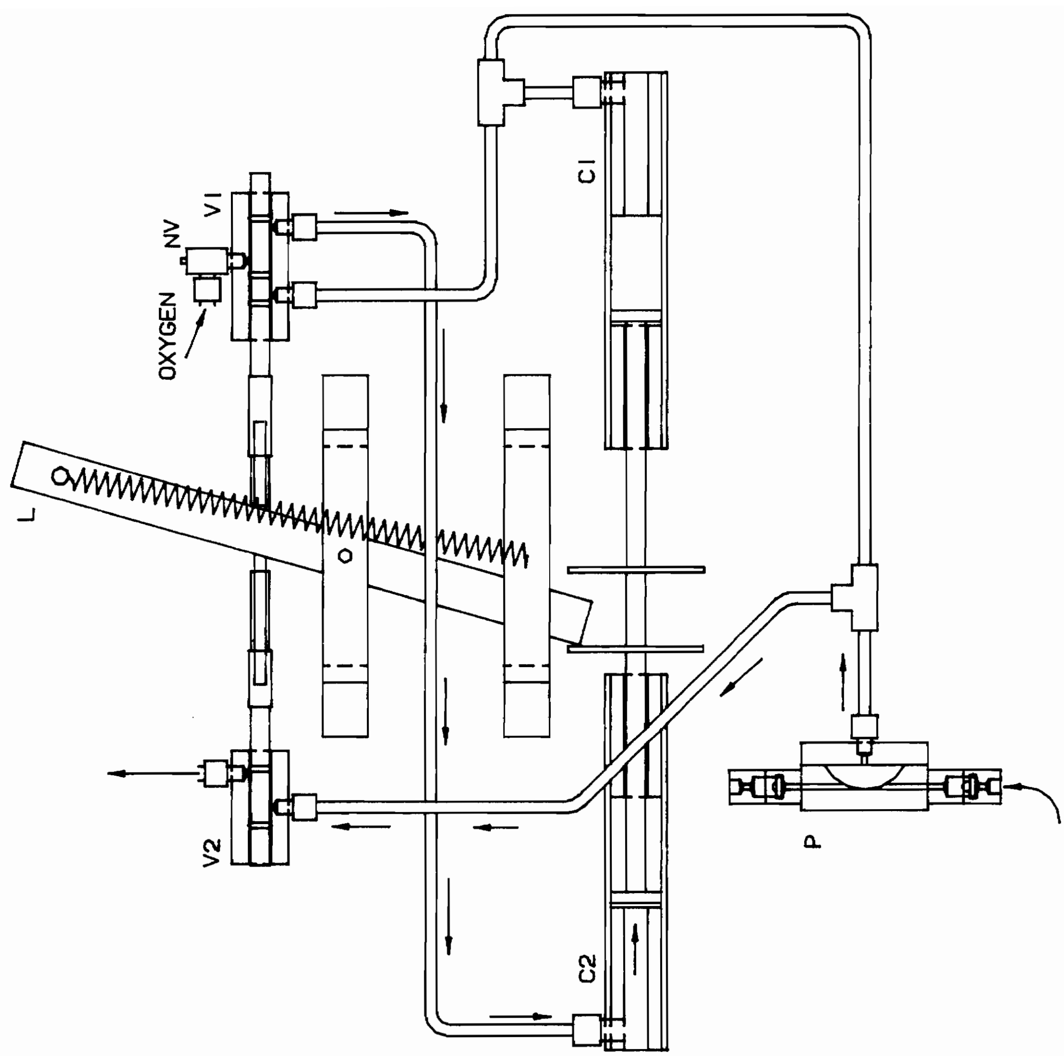

Figure 1. Pump Apparatus, Position 1

Referring again to Figure 1 on page 8, cylinder C1 and cylinder C2 provide the driving force to move lever arm L. Pressure buildup in one of the cylinders cause plungers to move, thereby moving the yoke, which moves the lever arm, which, in turn, moves the oxygen valve shafts. The springs attached to both sides of the lever arm provide quick action once the lever arm tilts past centerline in the direction of motion. This positive action is necessary to keep the pump apparatus moving; otherwise, the oxygen valve shafts would stall in an intermediate position.

The cylinders are commercial cylinders constructed of brass tubes, stainless steel rods, and Buna N "T" rings and Buna N "V" ring seals. The cylinders are rated for temperatures of -34° to 110° C (-30° to 230° F) and will be exposed to oxygen gas within a range of 2° C (36° F) to room temperature. The cylinder shafts are connected together via a threaded nut. The yoke located on the connected cylinder shafts consists of two plates, held in place with nuts. The lever arm is constructed of brass and contains three holes: upper hole for spring attachment via a 10-24 screw, center hole for connection to oxygen valve shafts, and the lower hole for the steel dowel pin which acts as the lever arm pivot rod. The springs attached to the lever arm are constructed of steel and were chosen through experimentation with different spring sizes and strengths.

The diaphragm pump of Figure 1 is driven by the pulsing oxygen source provided by the pump apparatus. The diaphragm pump is located below the surface level of the perfusion fluid in the organ bath, therefore perfusion fluid from the organ fluid bath fills the pump cavity as a result of fluid head. Perfusion fluid on one side of the diaphragm is expelled from the diaphragm pump as a result of room temperature oxygen gas pressure on the other side of the diaphragm, as supplied by the pump apparatus.

The diaphragm pump body is made of plexiglas with a silicone rubber diaphragm. The diaphragm pump body contains a 1.5 ml (0.0915 in^3) cavity into which the pumped perfusate fluid will flow from the organ bath. The diaphragm pump lid compresses a silicone rubber diaphragm into the diaphragm pump body. The diaphragm separates the fluid in the cavity from the oxygen, yet allows gaseous oxygen through to oxygenate the perfusate. Fluid flows into and out of the diaphragm pump via 1.59 mm (0.0625 in.) diameter holes connecting to the body cavity. Check valves constructed of plexiglas, with o-ring seats and glass ball stoppers, are connected to the inlet and outlet holes to allow flow to enter in the bottom and exit from the top of the diaphragm pump. Connection of check valves to the diaphragm pump body was accomplished by chemically welding the plexiglas with dichloromethane. Detail drawings are contained in Appendix A.

3.2.2 Pump Function

The pump apparatus functions as follows. Consider the pump apparatus to be in Position 1 shown in Figure 1. At this point, lever arm L has just been pulled to the right by the action of the oxygen pressure in cylinder C1, and the springs. Oxygen which had been pressurizing diaphragm pump P is allowed to escape via the tubing which tees off the oxygen supply line to oxygen outlet valve V2. Used oxygen from diaphragm pump P is released through oxygen outlet valve V2 to the vent. As the pressure is released from diaphragm pump P, the fluid head causes the diaphragm pump cavity to fill with perfusate. Source oxygen flow is controlled by needle valve NV and is channelled through oxygen inlet valve V1 through the bottom right opening in the valve casing. Stainless steel tubing directs the pressurized oxygen into cylinder C2. Pressure builds in cylinder C2 and begins to move the cylinder plunger. As the plunger moves, lever arm L, and every component connected to it, moves. Therefore, the two cylinder plungers and the yoke, the lever arm and the oxygen valve shafts move with pressure build-up.

Once lever arm L has been moved so the arm tilts just left of the centerline, the springs cause lever arm L to snap to its position of full travel, left tilt. By this action, all cylinder plungers and oxygen valve shafts have been settled into Position 2, shown in Figure 2. In this position, oxygen is channelled through needle valve NV and oxygen inlet valve V1 to the bottom left opening in the valve casing. Tubing leads the oxygen to the inlet of cylinder C1, to the inlet on the lid of diaphragm pump P, and into oxygen outlet valve V2. Pressurization begins in cylinder C1 while diaphragm pump P is pressurized and pushes fluid out the top check valve. The o-rings in oxygen outlet valve V2 have sealed the inlet of the valve so that no oxygen can escape, thus allowing the pressurization of diaphragm pump P and cylinder C1.

As pressure builds in cylinder C1, the plunger begins to move to the left, moving lever arm L, plunger of cylinder C2, the yoke, and oxygen valve shafts along with it. As lever arm L passes the centerline and begins its tilt to the right, the springs exert a force that pulls the lever arm, oxygen valve shafts and cylinder plungers to their full travel, right tilt, as shown in Figure 1.

Oxygen inlet valve V1 now directs oxygen to cylinder C2 and the entire cycle is repeated. Each cycle consists of the tilting of lever arm L from right to left to right again and causes diaphragm pump P to deliver fluid once. The rate of the pump must be adjusted via the needle valve which controls flow of oxygen from the oxygen reservoir.

3.2.3 Pump Testing

Testing of the pump was done to show that the pump could move perfusate at a rate of 10-25 ml/min (0.615 - 1.536 in^3/min). The pump was initially tested using a 150 kPa (22 psig) compressed air source instead of the intended oxygen boiled off from the Dewars flask. A connection of tygon® tubing from the compressed air source to the stainless steel tubing was necessary to enable tests to be run. A 610 mm (24 in.) length of stainless steel tubing was used to simulate the path of the supply of oxygen in the actual preservation cooler configuration.

In tests, water was used as a substitute instead of using an actual perfusate solution such as Ringer's lactate solution. Ringer's lactate solution and water are similar in density and viscosity, so the substitution is valid.

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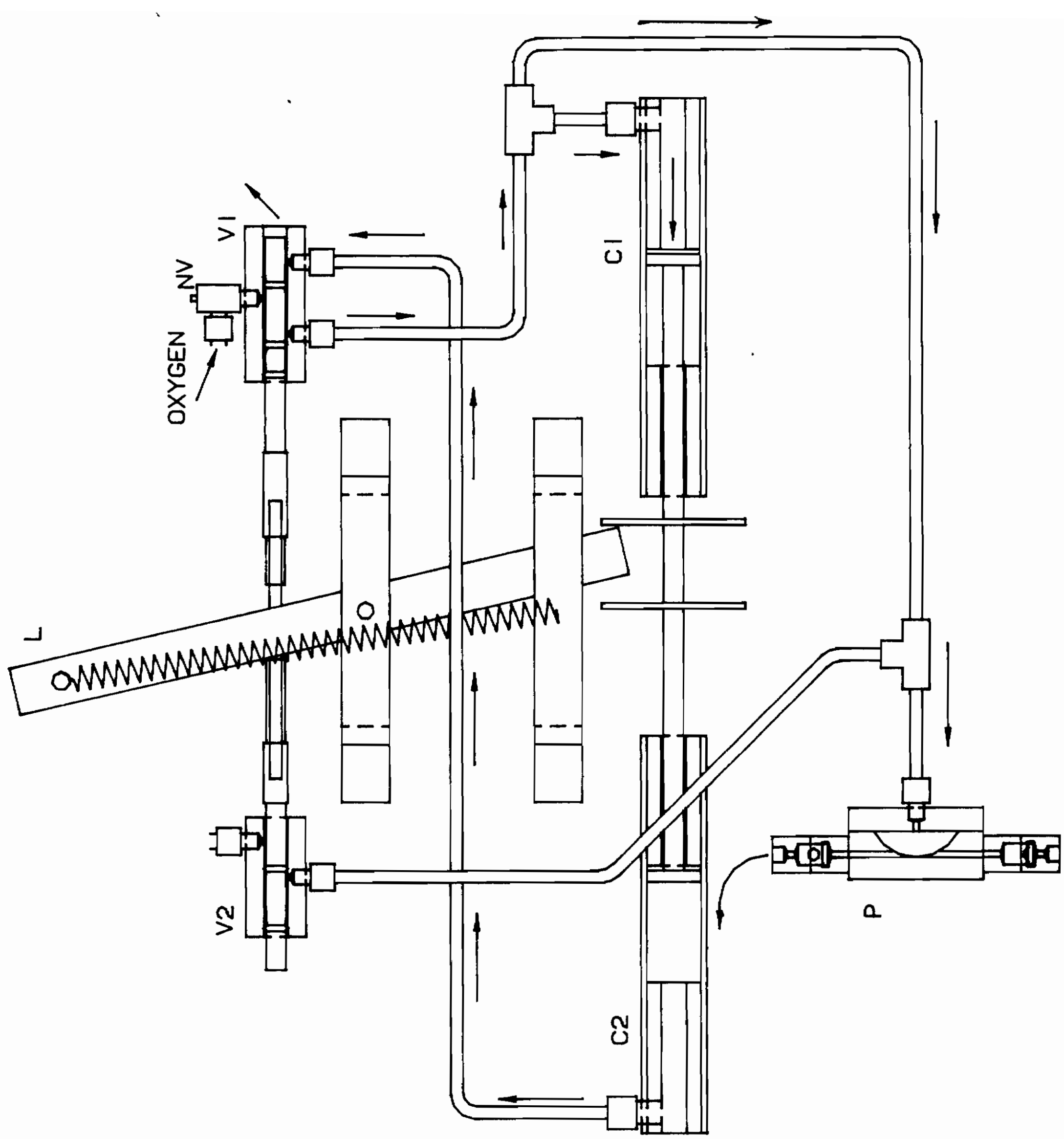

Figure 2. Pump Apparatus, Position 2

A water reservoir was located such that the surface of the water was located 152 mm (6 in.) above the diaphragm pump, simulating the location of the pump within the actual preservation cooler. The needle valve on the pump apparatus was adjusted to provide water flow through the pump from 10 - 25 ml/min (0.615 - 1.536 in^3/min). Pump output was measured using a graduated cylinder.

Upon completion of these preliminary tests, the pump was then powered by nitrogen boiled off from the Dewars flask. Nitrogen was substituted for oxygen because it is readily available on campus and it boils at a temperature of -196° C (-321° F), similar to oxygen which boils at -183° C (-297° F) readily available on campus. During the final testing stage, the pump apparatus and temperature control device were tested together to prove that the nitrogen (oxygen) source would be able to both cool the organ bath and power the pump. Nitrogen was channelled directly into the open loop heat exchanger tubing within a cooler and the exit gas was used to power the pump. Pump rate was recorded at 15 minute intervals. Gas consumption was then determined.

3.3 Temperature Control and Maintenance

Two options were considered for controlling or maintaining the temperature in the transplant organ preservation cooler. One option for the temperature control device used in the preservation cooler uses a closed loop system in which the movement of a bimetallic coil is used to control the flow of oxygen exiting the Dewars flask tubing. As the temperature of the organ bath rises above 2° C (36° F), linkages attached to the bimetallic coil move as the bimetallic coil moves with the temperature change of the perfusion fluid. These linkages in turn rotate shafts in butterfly valves which direct exiting oxygen gas through the cooling valve to the cooling coils within the organ bath. At 6° C (43° F), the cooling valve is open and the vent valve is closed. If the organ bath is within the temperature range of 2° - 6° C (36° - 43° F), exiting oxygen is able to move through both the open cooling valve to cool the organ bath and through the open vent valve to vent to atmosphere. At 2° C (36° F) or below, the oxygen vent valve is open and the cooling valve is closed.

The second option for temperature maintenance in the preservation cooler is an open loop system in which tubing is run directly from the Dewars flask into the organ bath. The heat exchanger tubing within the bath is located on the bottom of the vessel. The organ bath fluid is pre-cooled to 2° - 3° C (36° - 37° F) with ice. Oxygen boiling off from the Dewars flask reservoir is cool enough to maintain the organ bath temperature. The oxygen then exits the organ bath and goes on to power the pump apparatus.

3.3.1 Temperature Control and Maintenance Device

Closed loop option one for the preservation cooler temperature control device consists of a bimetallic coil, linkage system, oxygen exit chamber, vent and cooling valves, and cooling coils within the organ bath. Figures 3 and 4 illustrate option one of the temperature control device arrangement. Bimetallic coil BC is mounted in a box which separates it from the organ bath to avoid contamination of the organ. The coil box is filled with perfusate and situated within the organ bath to allow the bimetallic coil to detect the temperature of the organ bath. A system of linkages (L1, L2 and L3) connects the bimetallic coil to the shafts of the cooling and vent butterfly valves, CV and VV. Oxygen exiting the Dewars flask is directed through a tee, part of the flow going to power the pump, and the other flowing into the oxygen exit chamber, OEC, where the oxygen is contained at low pressure. The butterfly valves are located on oxygen exit chamber OEC and direct flow of exiting oxygen either through cooling valve CV to cooling coils within the organ bath, or through vent valve VV to be vented to atmosphere.

The bimetallic coil used in the prototype temperature control device was obtained from an automatic choke unit on an automobile carburetor. The bimetallic coil is mounted within a plexiglas

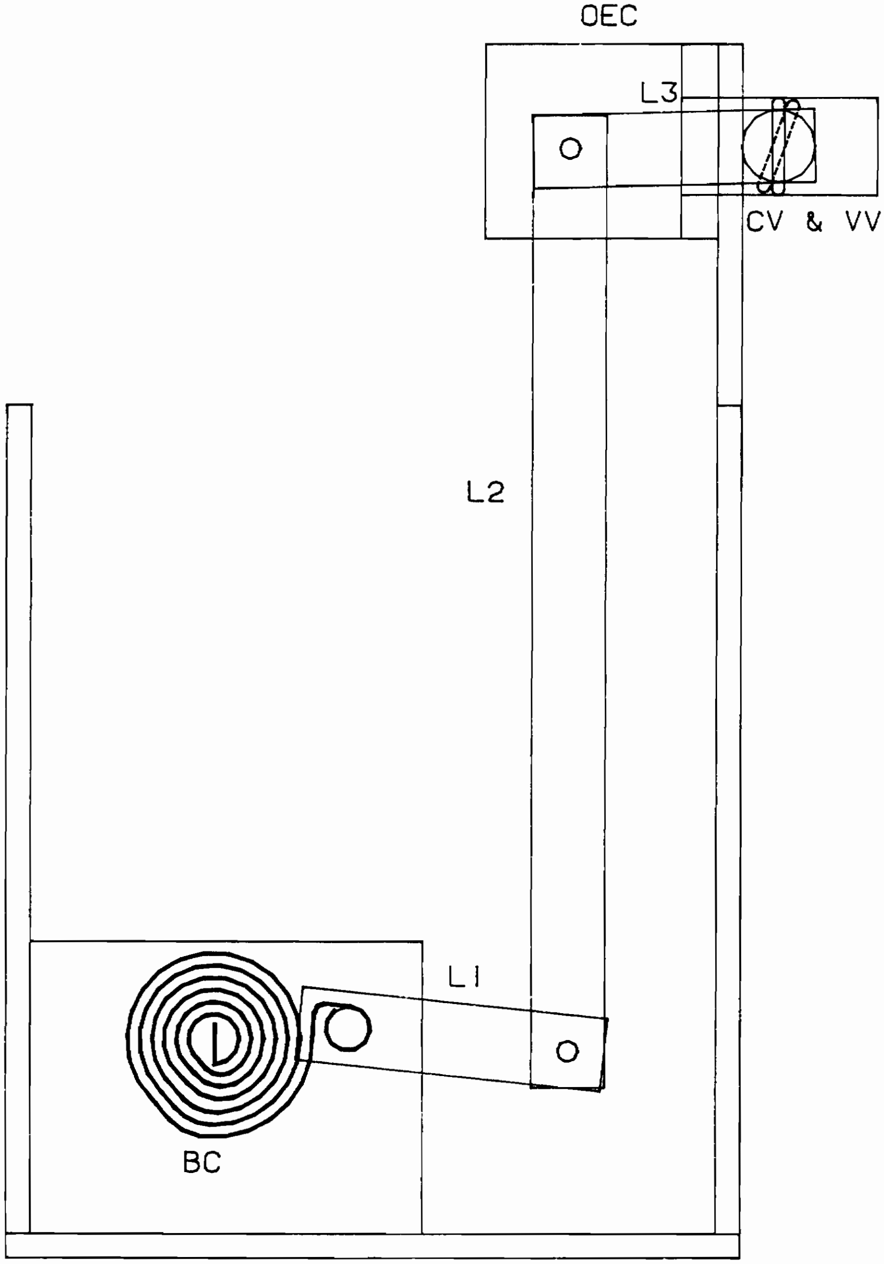

Figure 3. Temperature Control Device, Option One, Bimetallic Coil and Linkages

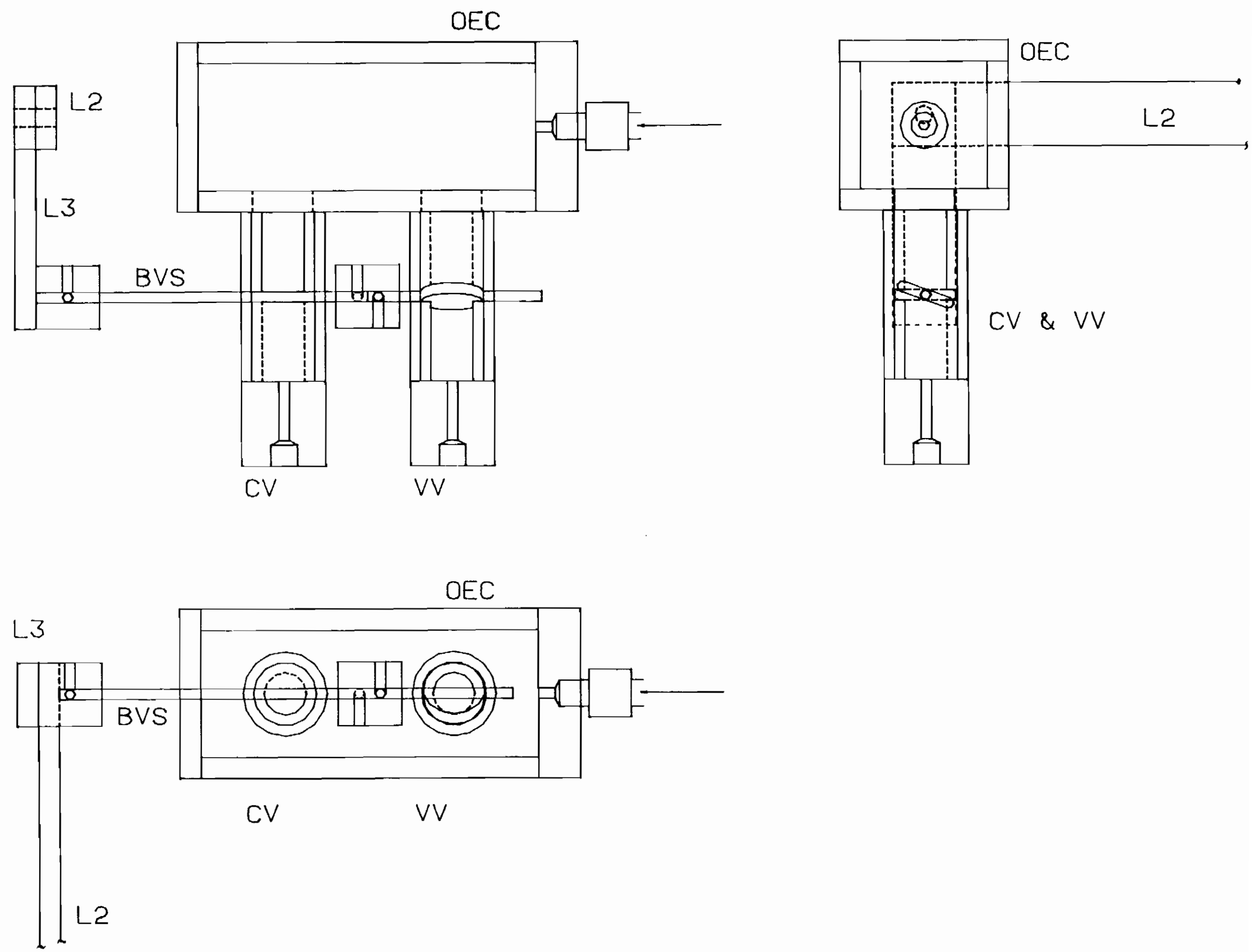

Figure 4. Temperature Control Device, Option One, Oxygen Exit Chamber with Vent and Cooling Valves

box. The linkage system is also constructed of plexiglas to provide lightweight links. Detail drawings are included in Appendix B.

The oxygen exit chamber is a small plexiglas box in which oxygen boiled off from the Dewars flask is directed out one of two butterfly valves. Vent and cooling butterfly valves on the exit chamber are constructed of plexiglas with brass plates and brass shafts. One end of the connected brass shafts is connected to the linkage system. The connected brass shafts of the vent and cooling valves are situated such that at extreme ends of the desired temperature range (2° - 6° C; 36° - 43° F) the valve plates are oriented wherein only one valve is open at a time. Movement of the bimetallic coil due to temperature changes will cause the valve shafts to rotate, closing one valve and opening the other. Coils of stainless steel tubing within the organ bath act as the heat exchanger. Detail drawings of parts are located in Appendix B.

The second option for cooling the organ bath consists of an open loop system in which coils of stainless steel heat exchanger tubing are placed within the organ bath. Oxygen which has boiled off from the Dewars flask is channelled directly into the heat exchanger tubing. Liquid within the organ bath is pre-cooled to 2° - 3° C (36° - 37° F) with ice, and temperature is maintained by the cool temperature of the boiled off oxygen. The length of the heat exchanger tubing is 4.6 m (15 ft). All tubing leading from the Dewars flask to the surface of the organ bath is insulated. Gas exiting the organ bath heat exchanger is directed to the pump apparatus input and is used to power the pump.

3.3.2 Temperature Control and Maintenance Device Function

Closed loop option one of the temperature control device functions as follows. Consider the temperature control device to be in the Position 1 shown in Figure 5. In this position, bimetallic coil BC is within a perfusate bath sensing an organ bath temperature of 2° C (36° F). Linkages L1, L2 and L3 and butterfly valve shafts BVS are located such that oxygen in oxygen exit chamber OEC is being directed out open vent valve VV.

As the temperature of the organ bath rises, the loop on bimetallic coil BC rotates counterclockwise. The linkages L1, L2 and L3 and connected butterfly valve shafts (BVS) have been situated such that when the temperature reaches 6° C (43° F), butterfly valve shafts (BVS) have rotated, opening cooling valve CV and closing vent valve VV. Oxygen flows through cooling valve CV into the coils of the heat exchanger, placing the temperature control device in Position 2 shown in Figure 6.

As the oxygen cools the organ bath, the loop on bimetallic coil BC rotates clockwise. Attached linkages L1, L2 and L3 and butterfly valve shafts BVS then move back to a position wherein exiting oxygen is channelled out open vent valve VV, while cooling valve CV is closed, returning to Position 1 shown in Figure 5. Note that in this option for temperature control, oxygen is wasted while it is vented to atmosphere.

The function of temperature maintenance in open loop option two is the channelling of boiled off oxygen from the Dewars flask through heat exchanger tubing and exiting to power the pump apparatus. The temperature of pre-cooled perfusate is maintained by the cool temperature of the boiled off oxygen running through the heat exchanger tubing. Flow rate of the oxygen through the tubing may be controlled by the needle valve on the pump apparatus. Cooling is thus controlled by controlling the flow rate of the oxygen through the heat exchanger tubing. In this option, oxygen gas is conserved by using it first to cool the organ bath, and then to power the pump, rather than splitting the gas supply to power the pump and control temperature with a vent to atmosphere as done in option one.

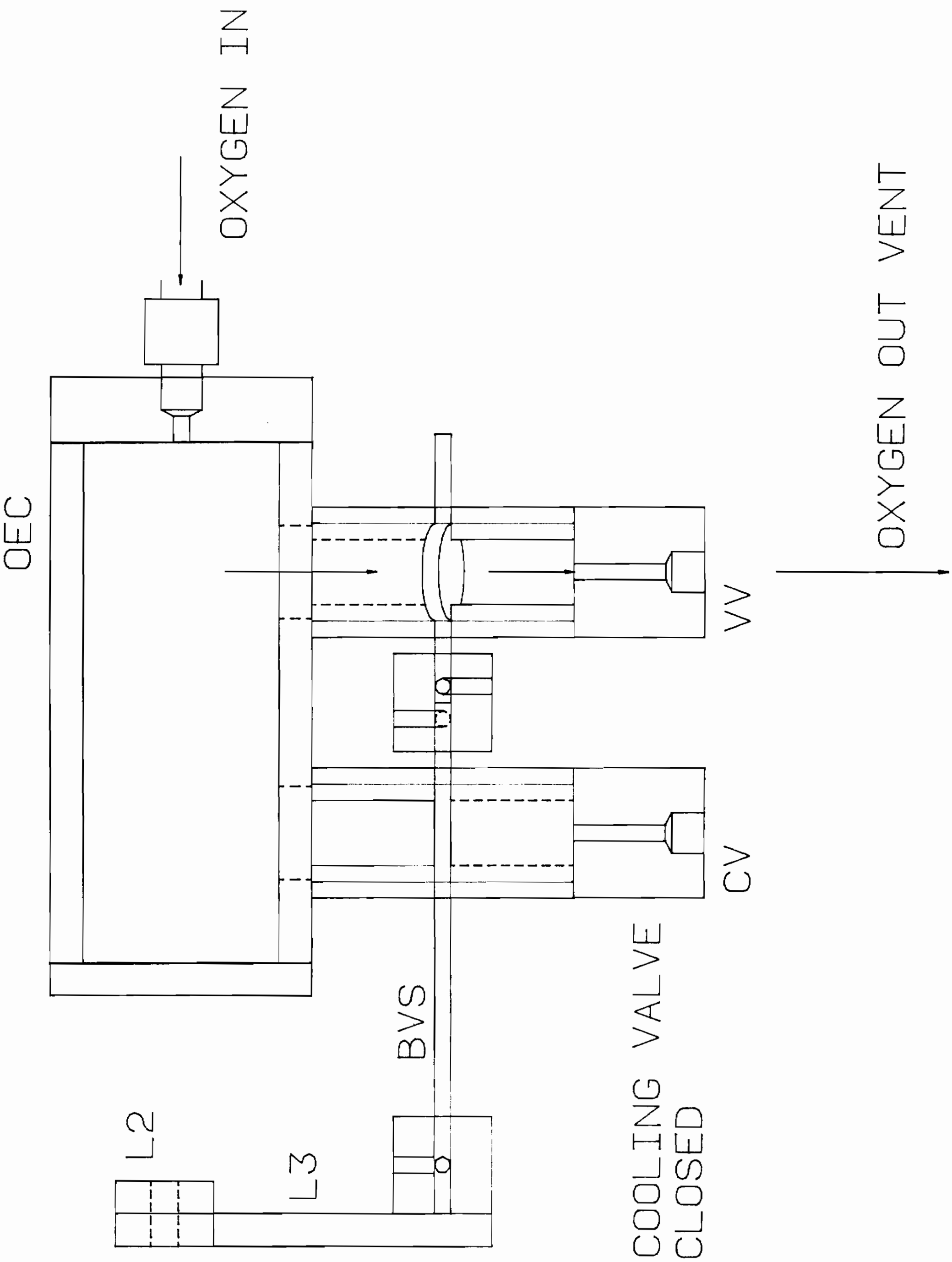

Figure 5. Temperature Control Device, Option One, Position 1

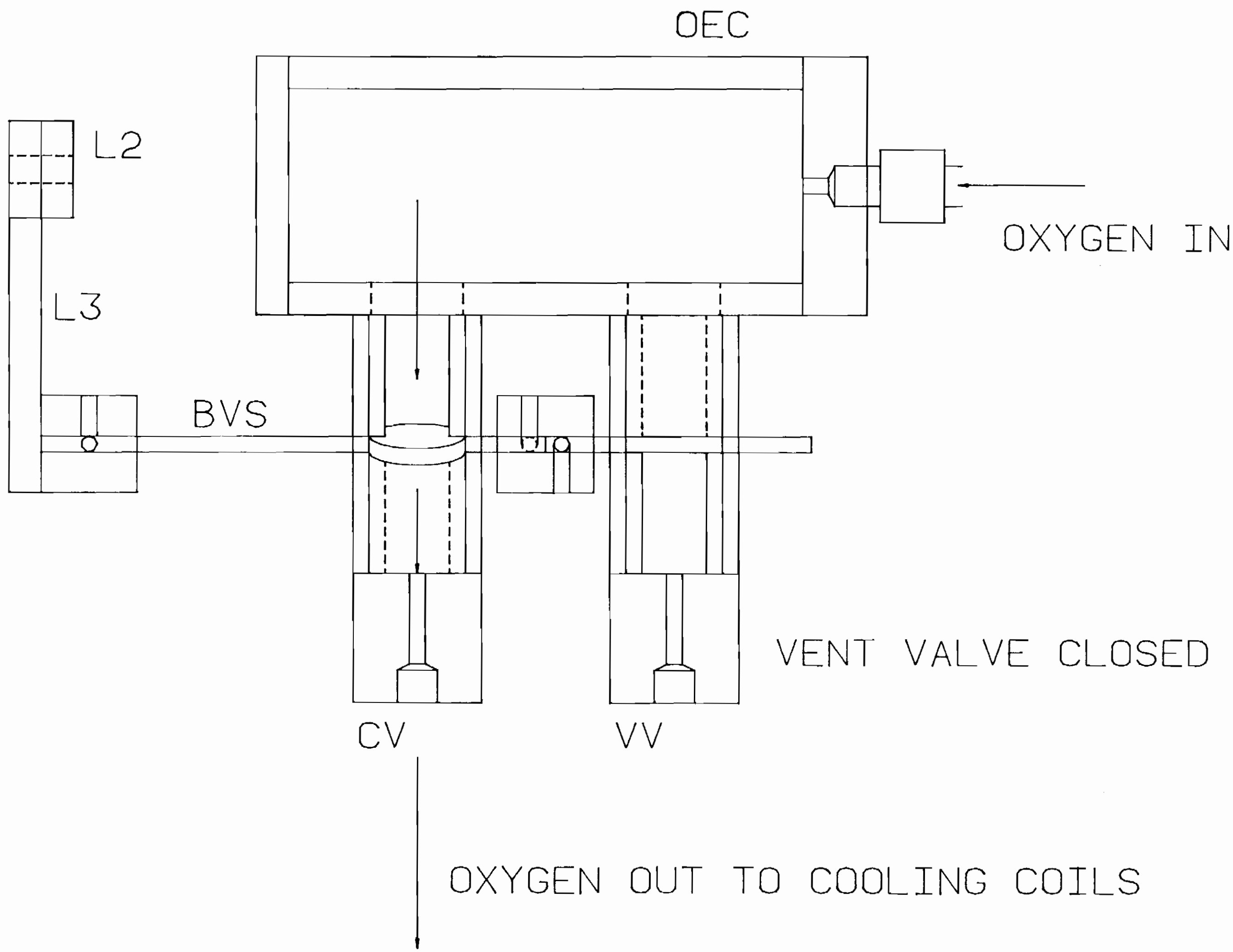

Figure 6. Temperature Control Device, Option One, Position 2

3.3.3 Temperature Maintenance Device Testing

The temperature maintenance device was tested using nitrogen boiled off from the Dewars flask to cool the organ bath. Again, nitrogen was used instead of oxygen because it is readily available on campus and boils near the same temperature as oxygen. From observation of the Dewars flask, rate of nitrogen boil off, and to conserve gas, testing was done using open loop option two, direct channelling of nitrogen into the heat exchanger, to maintain the temperature of the organ bath. Cooling coils of stainless steel, fastened to a piece of plexiglas to maintain shape, were placed in a 15 L (4 gal) cooler and were covered with 101.6 mm (4 in.) of water. Ice was used to pre-cool the water to 2° - 3° C (36° - 37° F).

Temperature of the simulated organ bath was monitored using a mercury thermometer and was checked at fifteen minute intervals. Test duration varied from 5 to 10 hours, depending on the gas supply available from the Dewars flask. Two different situations were used to test the effectiveness of the open loop temperature maintenance device. Room temperature ambient conditions were used first, and upon successful testing, the temperature maintenance device was tested in ambient conditions of the extreme warm (40° C, 105° F) condition expected. To simulate the warm conditions, a container was created using a 0.2 m^3 (6 ft^3) metal cart enclosed by cardboard sides. A hairdryer was positioned to maintain container temperature between 38° and 42° C (100° and 108° F). In tests simulating warm conditions, both the temperature was maintained and the pump was powered by the nitrogen boiling off from the Dewars flask.

4.0 Results

Results of the pump tests and the temperature control device tests are included below. Data of interest during the transplant organ preservation cooler testing includes pump rate, gas consumption, cooler temperature, and ambient temperature.

In measuring pump rate, strokes per minute were used. A stroke consists of the movement of the pump apparatus lever arm from one side to the other. Note that an entire cycle, consisting of two pump apparatus strokes, is necessary to pump fluid from the diaphragm pump once. Gas consumption was based on the volume of the pump apparatus (cylinders, tubing and diaphragm pump), with gas pressure at 150kPa (22 psig) at room temperature (22° C; 72° F). Assuming the pump apparatus is cleared of gas for each pumping cycle, gas consumption was calculated from the pump rate.

Six tests were run. Table 1 shows which device was tested, the power source used and the ambient conditions for each test.

Average values of pump rate, gas consumption, cooler temperature and ambient temperature were calculated for each test, where applicable. The range of values for each of these items was also

Table 1. Test Conditions for Six Preservation Cooler Tests

Test	Device Used	Power Source	Ambient Conditions
1	Pump	Compressed Air	Room Temperature
2	Pump	Nitrogen	Room Temperature
3	Temperature Control	Nitrogen	Room Temperature
4	Pump and Temperature Control	Nitrogen	Warm Temperature
5	Pump and Temperature Control	Nitrogen	Warm Temperature
6	Pump and Temperature Control	Nitrogen	Warm Temperature

noted. Average and range values for each test are shown in Tables 2 and 3. All test data is included in Appendix C.

Table 2. Average and Range Values for Pump Rate and Gas Consumption in Transplant Organ Preservation Cooler Tests

Test		Pump Rate (stroke/min)	Gas Consumption* (ml/min)	(in^3/min)	Gas Temperature (° C)	(° F)
1	Average	53.5	202.6	12.36	22	72
	Range	52-56	197.0-212.1	12.02-12.94	--	--
2	Average	46	174.3	10.63	22	72
	Range	38-55	143.9-208.4	8.78-12.71	--	--
3	Average	--	--	--	--	--
	Range	--	--	--	--	--
4	Average	90	342.1	20.87	38	100
	Range	66-120	250.0-454.6	15.25-27.73	33-41	91-106
5	Average	47	178.4	10.88	40	105
	Range	28-66	106.1-250.0	6.47-15.25	36-42	97-108
6	Average	52	196.7	12.00	40	105
	Range	47-55	178.0-208.4	10.86-12.71	34-42	93-108

*Gas at 150 kPa (22 psig)

Table 3. **Average and Range Values for Cooler Temperature and Ambient Temperature in Transplant Organ Preservation Cooler Tests**

Test		Cooler Temperature (° C)	(° F)	Ambient Temperature (° C)	(° F)
1	Average	--	--	22	72
	Range	--	--	--	--
2	Average	--	--	22	72
	Range	--	--	--	--
3	Average	3.7	39	22	72
	Range	2.0-6.0	36-43	--	--
4	Average	3.5	38	37.8	100
	Range	3.0-5.0	37-41	33.0-41.0	91-106
5	Average	3.9	39	40.4	105
	Range	3.0-5.5	37-42	36.0-42.0	97-108
6	Average	3.0	37	40.4	105
	Range	2.0-4.5	36-40	34.0-42.0	93-108

5.0 Discussion

The tests run with the transplant organ preservation cooler prove that the pump and the temperature maintenance device function. Each component of the preservation cooler is evaluated in the following sections.

5.1 Evaluation of Components

Tests run to prove the functionality of the preservation cooler pump and temperature maintenance device produced some differences in length of time that nitrogen was available to power the preservation cooler. Differences in test duration may be attributed to the amount of nitrogen available in the Dewars flask at the beginning of the tests. The Dewars flask was filled by pouring liquid nitrogen into the Dewars flask opening until full. Some nitrogen may have boiled off before capping the Dewars flask with the tubing connections. Possible system leaks, incomplete filling of the Dewars flask with liquid nitrogen, and time elapsed between filling of the Dewars flask and beginning of the test may have created differences in the amount of nitrogen within the Dewars flask.

5.1.1 Pump Evaluation

During pump tests, the lowest rate attained was 28 strokes/min, or 19.6 ml/min (1.205 in^3/min). Target rates for the pump were between 10 and 25 ml/min (0.615 - 1.536 in^3/min). Although the lowest pump rate attained falls within this range, most pump data reveals higher pump rates. Problems such as leakage around pump apparatus tubing fittings and wearing of o-rings contribute to a loss of available gas pressure. The gas flow required to maintain temperature limited the low rate. Friction may also cause low pump rates to be difficult to achieve.

Careful machining of pump apparatus parts, proper alignment of parts and adequate lubrication of o-rings and valve shaft sleeves will allow the pump apparatus to run smoothly and cut losses of power due to system inefficiency. Connections between pump apparatus parts and tubing fittings should be checked for leaks. Another possible option for achieving greater power from the boiled off oxygen is to use a pressure relief valve which is set higher than 22 psi, such as 25 psi or 30 psi.

5.1.2 Temperature Maintenance Evaluation

In all tests run to test the temperature maintenance device, cooler temperature was maintained within a 4° C (7.2° F) or smaller range. Variations in temperature maintenance could have been caused by the amount of nitrogen available in the Dewars flask, effectiveness of insulation and presence of leaks in the system.

The temperature maintenance system used in testing was insulated with rags wrapped around all exposed tubing, up to the surface of the water within the cooler. A plexiglas cover propped over the water surface in the cooler allowed air space within the cooler to be filled with rags to reduce heat transfer by convection. Cooling coils running in and out of the cooler caused the cooler lid to be constantly cracked open. In an actual perservation cooler set-up, well-insulated tubing and bulkhead penetrations into the cooler should be used to reduce losses. In this way, cooler temperatures should be able to be maintained for longer periods of time.

5.2 Improvement of Methods

Though the prototype preservation cooler has been successfully tested, possible improvements to the current design exist. Because the selection of materials and sizes for the prototype preservation cooler were limited, changes to these items for an actual unit is suggested.

Materials used in the prototype were those readily available for use. In an actual preservation cooler, care must be taken to use materials which are compatible with perfusate and pure oxygen. Also, lightweight materials would improve portability of the unit. If compatible plastic materials are available which are of sufficient strength, a smaller, more lightweight version of the pump apparatus could be formed.

A useful option for temperature maintenance would be to be able to set the temperature range within the preservation cooler to different values for different organs. For example, hearts are best preserved at 2 - 4° C (36 - 39° F) [5] while kidneys are generally stored in a 12 - 15° C (52 - 59° F) [2] temperature range. Variation in the temperature to which the organ bath is pre-cooled may be employed to set the desired temperature range.

Setting pump rate for temperature maintenance external to the preservation cooler is another practical option. In this way, the organ would not have to be disturbed in order to change pump rate. Careful positioning of internal parts in the cooler could allow needle valve NV, which controls oxygen flow into the pump apparatus, to be near the container edge and the valve stem to be accessible through the wall. This would create a seemingly "remote" operation, for the sake of convenience.

A method used to recharge the oxygen in the Dewars flask would have to be developed if oxygen needs to be refilled during preservation. This is dependent on the length of storage time required from the preservation cooler. Use of an alternate source port would be required while recharging and/or replacing the Dewars flask. A tee on the cooling coil inlet with a 3-way valve to change inlets could be used. Two Dewars flasks would be necessary for this option.

One possible alternative for the preservation cooler is to incorporate a microcontroller into the design. Although a power source would be required for the microcontroller and its various sensors, the convenience of information displays and the monitoring capabilities of the mirocontroller may outweigh this disadvantage. Items which could be monitored or regulated by the microcontroller include pump rate, temperature, amount of oxygen remaining and time elapsed during storage. Electrical sensors for monitored values would be required to interface with the microcontroller.

If low pump rates are not possible due to increased gas flow because of cooling requirements, the current arrangement of the cooling system and the pump in series could be changed. A parallel system in which the oxygen source is split to power the pump independently of cooling would allow separate control of the pump rate and cooling system.

6.0 Conclusions

Based on the success of the prototype pump and temperature control systems during testing, the principle design for the transplant organ preservation cooler is sound. The goal of simplicity and portability in a self-contained functioning unit has been attained. Refinement of the prototype pump and temperature control system into a lightweight and well-insulated model is recommended for clinical use of the preservation cooler.

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Appendix A. Pump Parts

Table 4. Parts List--Pump

Quantity	Part	Figure No.
1	Oxygen Inlet Valve Casing	7
1	Oxygen Inlet Valve Shaft	8
1	Oxygen Outlet Valve Casing	9
1	Oxygen Outlet Valve Shaft	10
5	No. 6 O-ring	--
5	10-32 to 1/8″ OD Tubing Fitting, Swagelok B-200-6-1	--
1	Needle Valve, Clippard MNV-1	--
1	Valve Shaft Conn. & Conn. to Lever Arm	12
1 each	Valve Shaft Sleeve	13
1	Lever Arm	14
1	Steel Dowel Pin	--
2	Steel Spring,1/32 Diameter, 3″	--
1	10-24 Screw, 2″; nut	--
2	Cylinder, Clippard H9C-1D	--
2	Cylinder Yoke	15
4	1/4-28 Thread Nut	--
1	Cylinder Shaft Connector	16
2	1/16″ NPT to 1/8″ Tubing Fitting, Swagelok B-200-1-1	--
1	Diaphragm Pump Body	17
1	Diaphragm Pump Lid	18
1	Diaphragm, Rubber, 1.4″ Square	--
2	Diaphragm Pump Check Valve, Pump Side	19
2	Diaphragm Pump Check Valve, Tube Side	20
2	No. 6 O-ring	--
2	Glass Beads, 0.135″ Diameter	--
4	Wire, Stainless Steel, 1/32″ Diameter, 1/4″	--
4	8-32 Screw, 1 1/4″	--
2	10-32 to 1/8″ Hose Fitting, Clippard 11752-1	--
1	10-32 to 1/8″ Tubing Fitting, Swagelok B-200-6-1	--
2	Oxygen Valve Support	21
1	Valve Shaft Sleeve Support, Left	22
1	Valve Shaft Sleeve Support, Right	23

Quantity	Part	Figure No.
2	Cylinder Support, Threaded End	24
2	Cylinder Support, Shaft End	25
6	Support Extender	26
1	Pump Support	27
4	Spacer for Diaphragm Pump Screw, 0.75″	--
1	Lever Arm Pivot Rod Support, 1	28
1	Lever Arm Pivot Rod Support, 2	29
1	Spring Support, 1	30
1	Spring Support, 2	31
1	Horizontal Support	32
1	Vertical Support	33
24	8-32 Screws, 1″	--
2	1/8″ OD Fractional Tube Tee, Swagelok B-200-3	--
762mm (30 in.)	1/8″ OD Stainless Steel Tubing	--

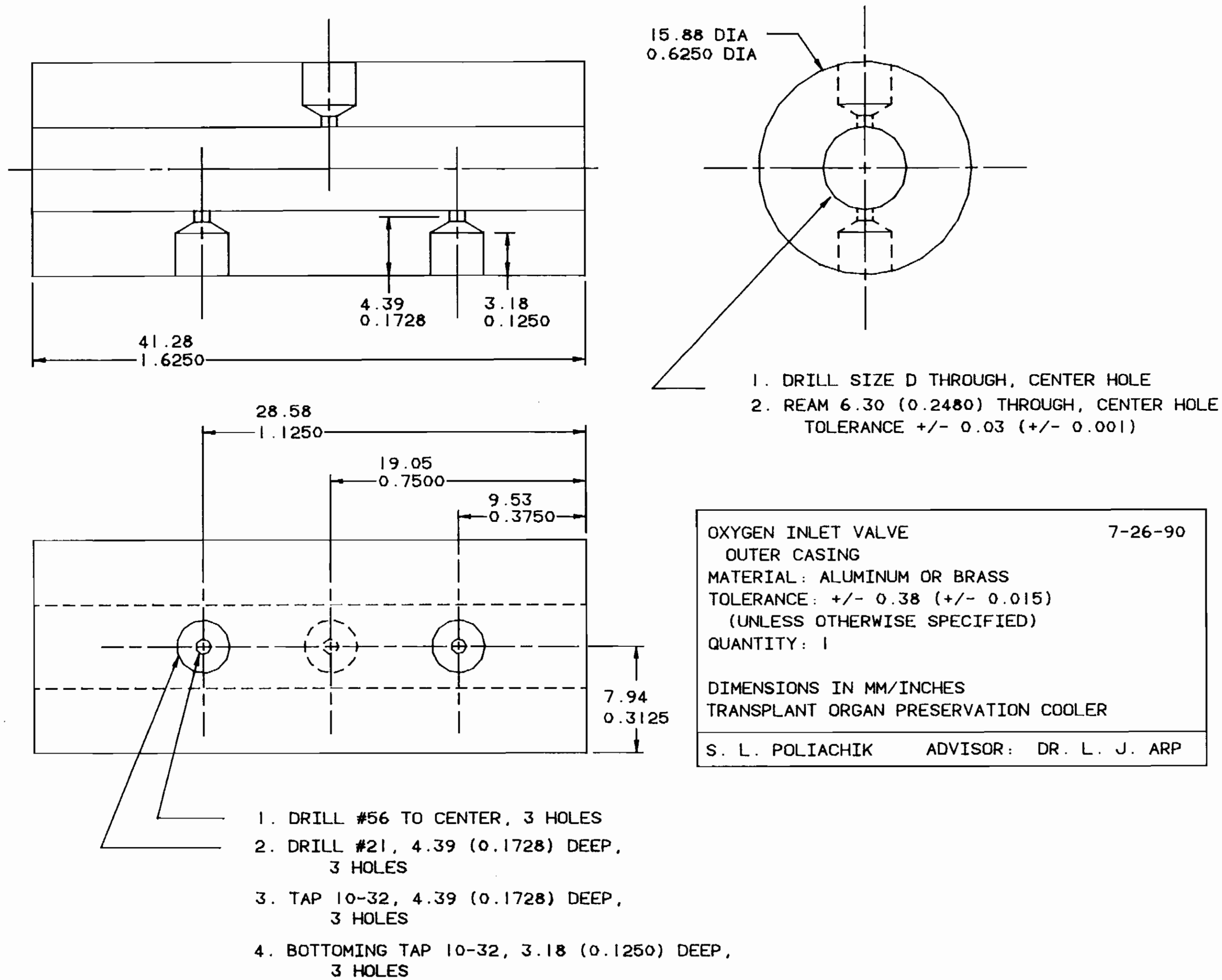


Figure 7. Pump Apparatus: Oxygen Inlet Valve Casing

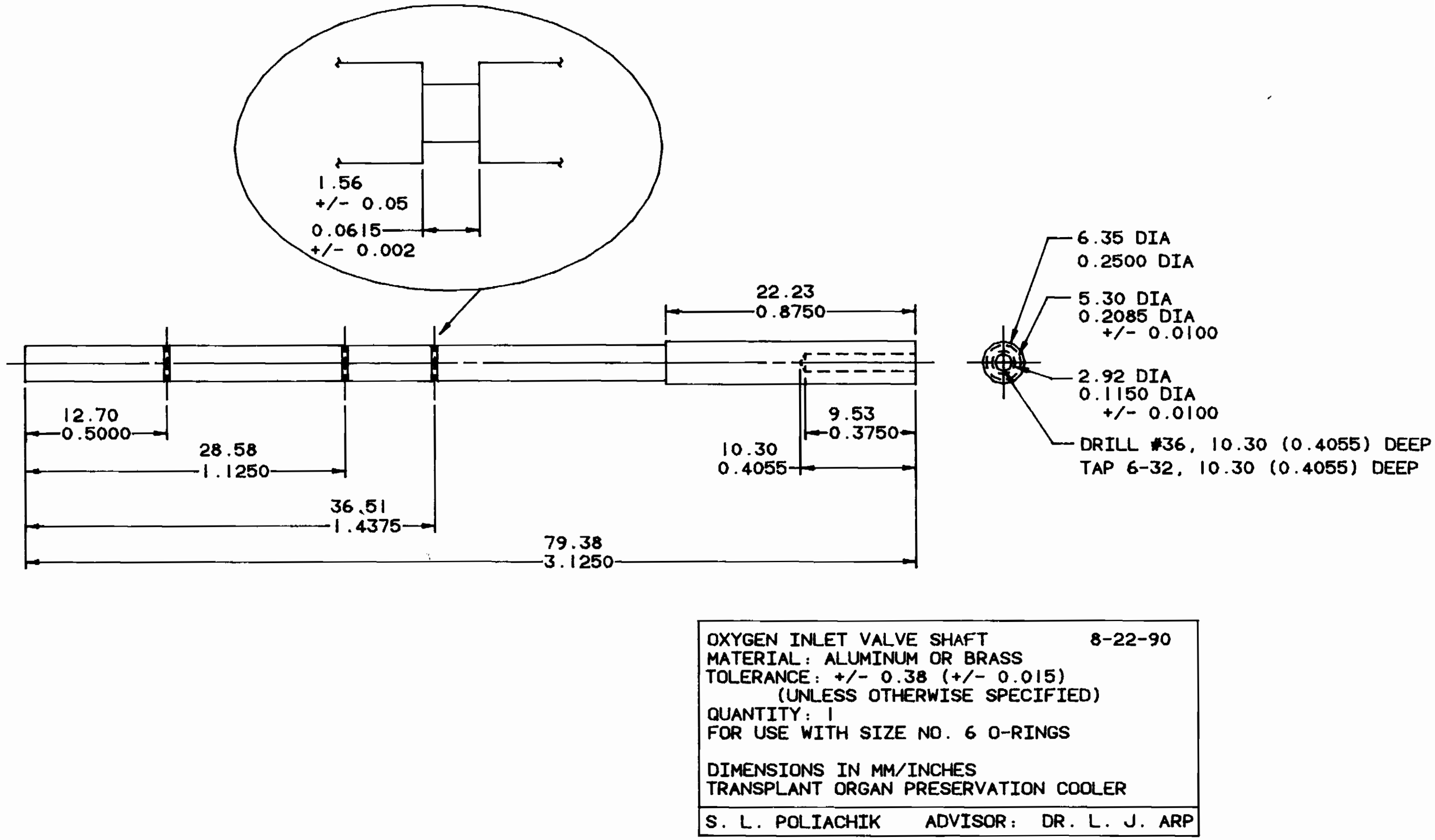


Figure 8. Pump Apparatus: Oxygen Inlet Valve Shaft

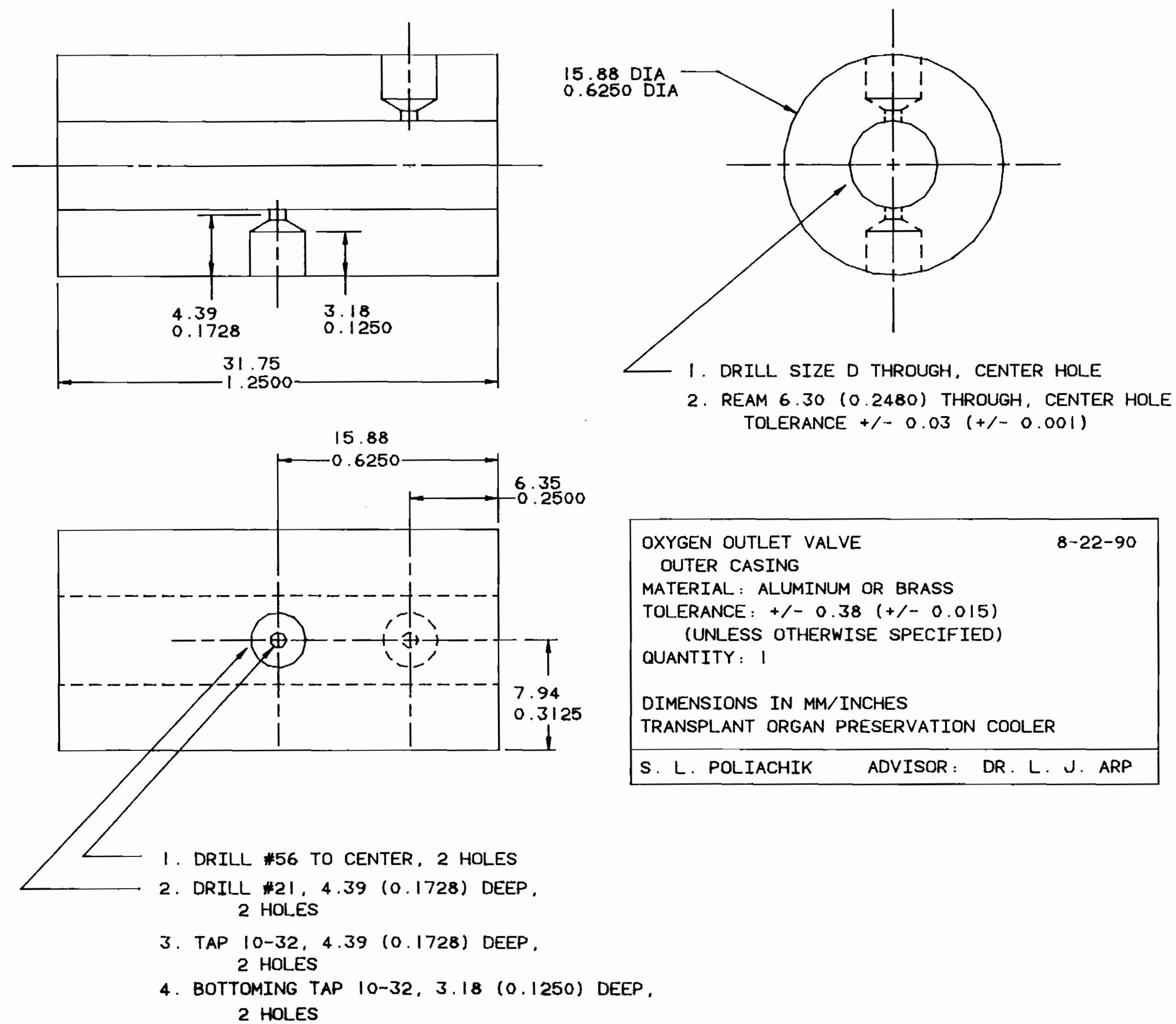


Figure 9. Pump Apparatus: Oxygen Outlet Valve Casing

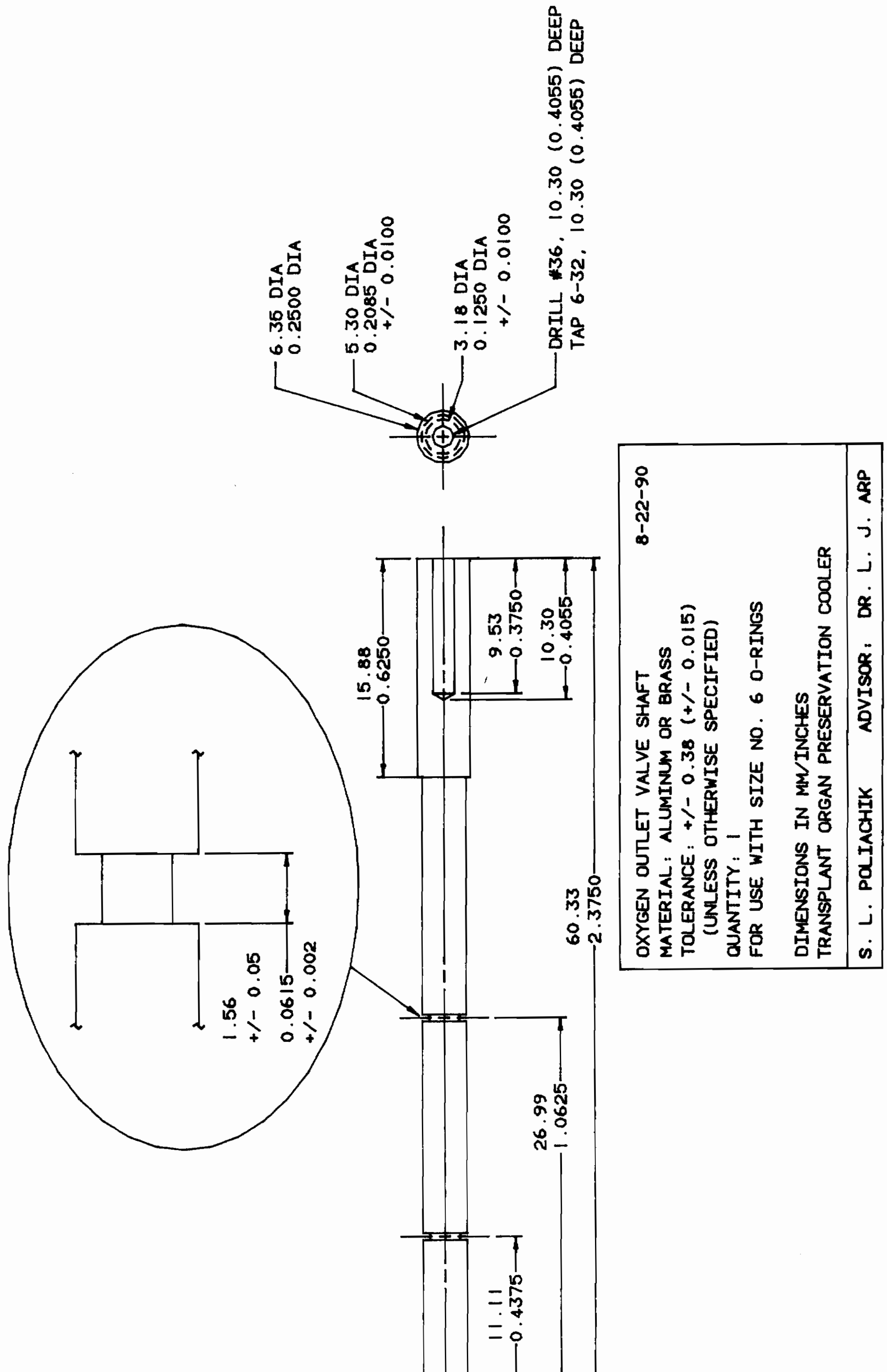


Figure 10. Pump Apparatus: Oxygen Outlet Valve Shaft

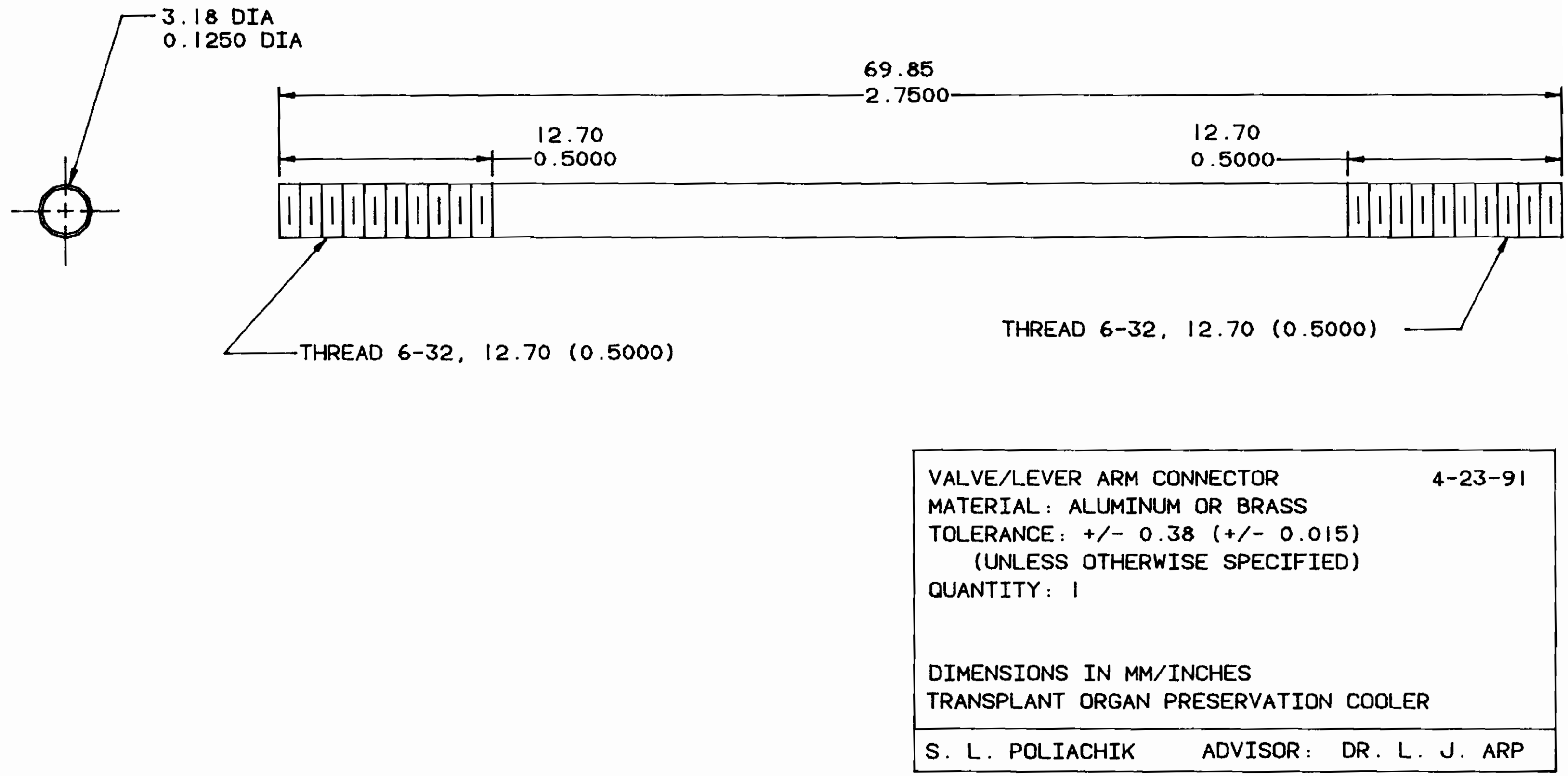


Figure 11. Pump Apparatus: Valve Shaft Connector and Connection to Lever Arm

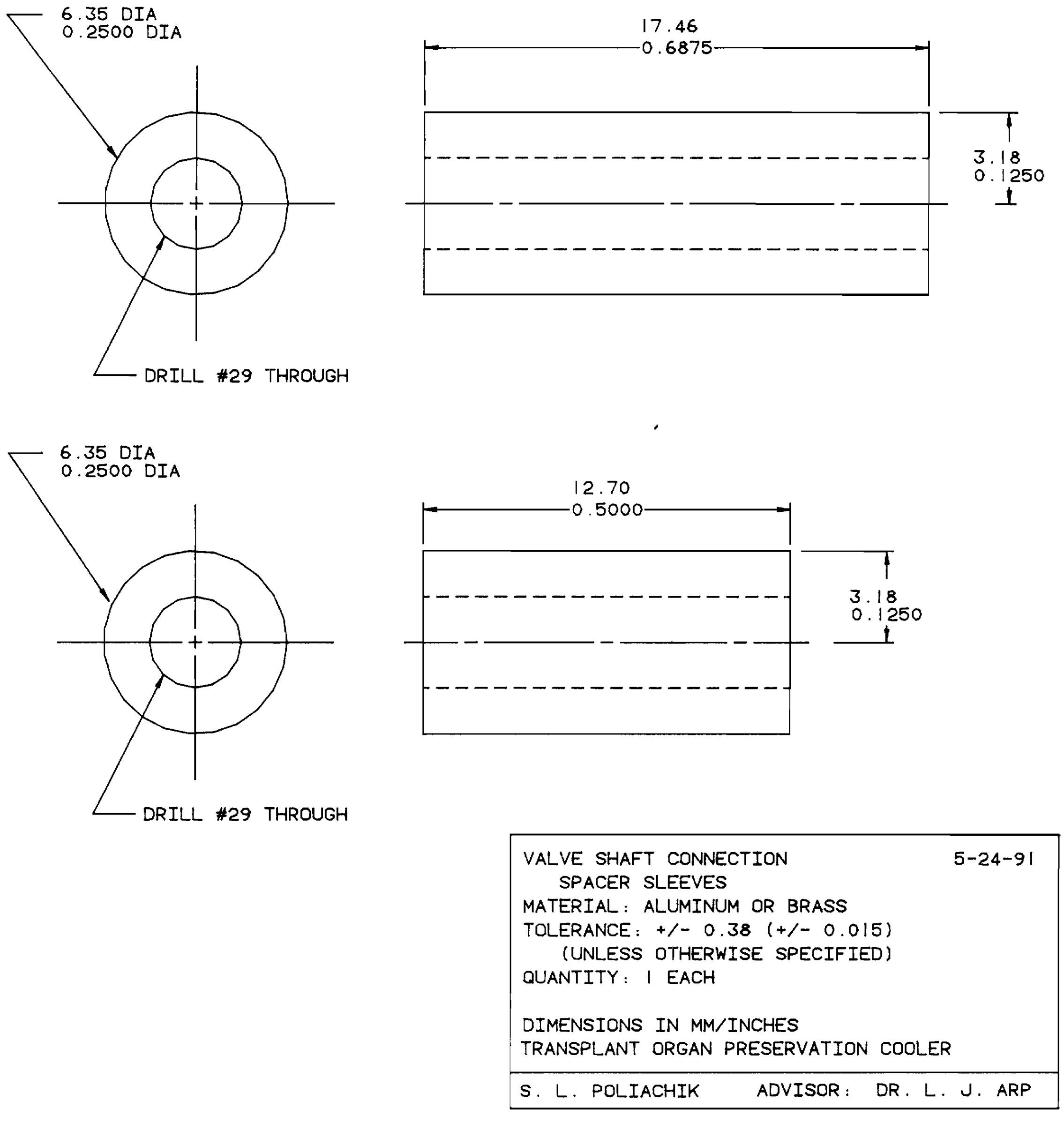
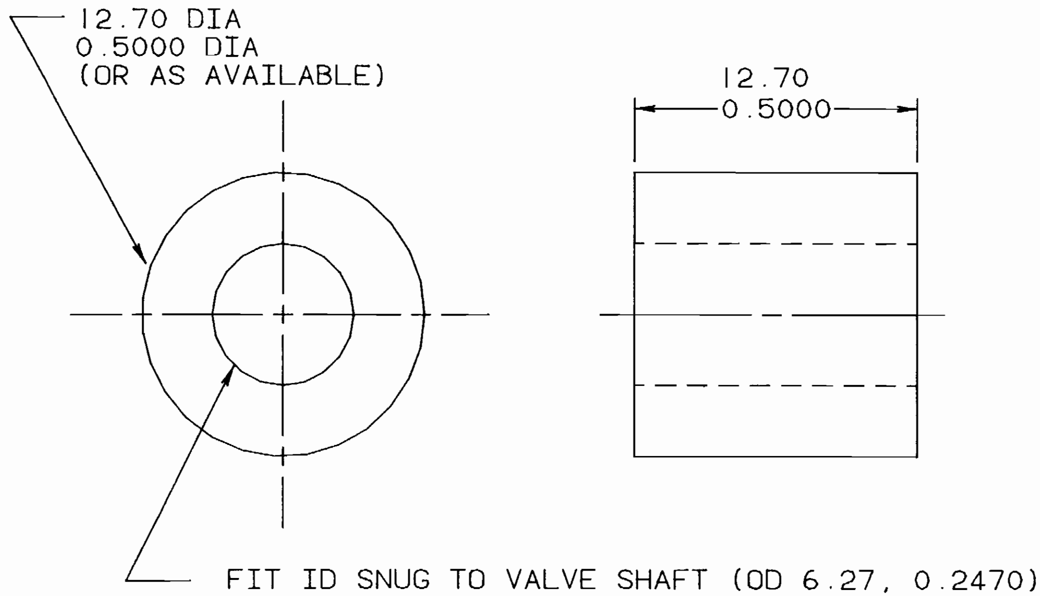


Figure 12. Pump Apparatus: Valve Shaft Connector Spacer Sleeves



VALVE SHAFT SLEEVE 5-14-91
MATERIAL: BRONZE OR BRASS
TOLERANCE: +/- 0.38 (+/- 0.015)
(UNLESS OTHERWISE SPECIFIED)
QUANTITY: 2

DIMENSIONS IN MM/INCHES
TRANSPLANT ORGAN PRESERVATION COOLER

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Figure 13. Pump Apparatus: Valve Shaft Sleeve

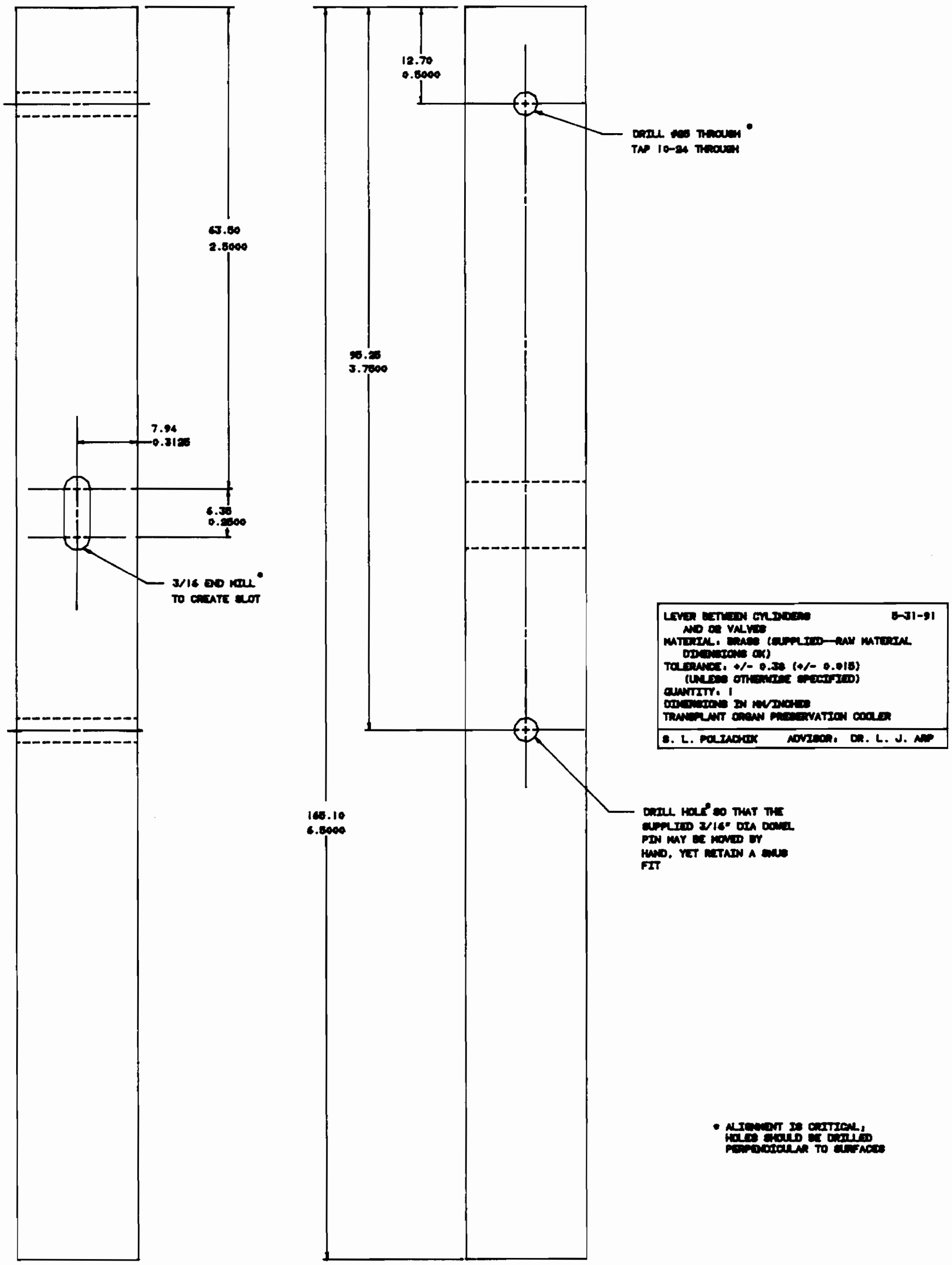


Figure 14. Pump Apparatus: Lever Arm

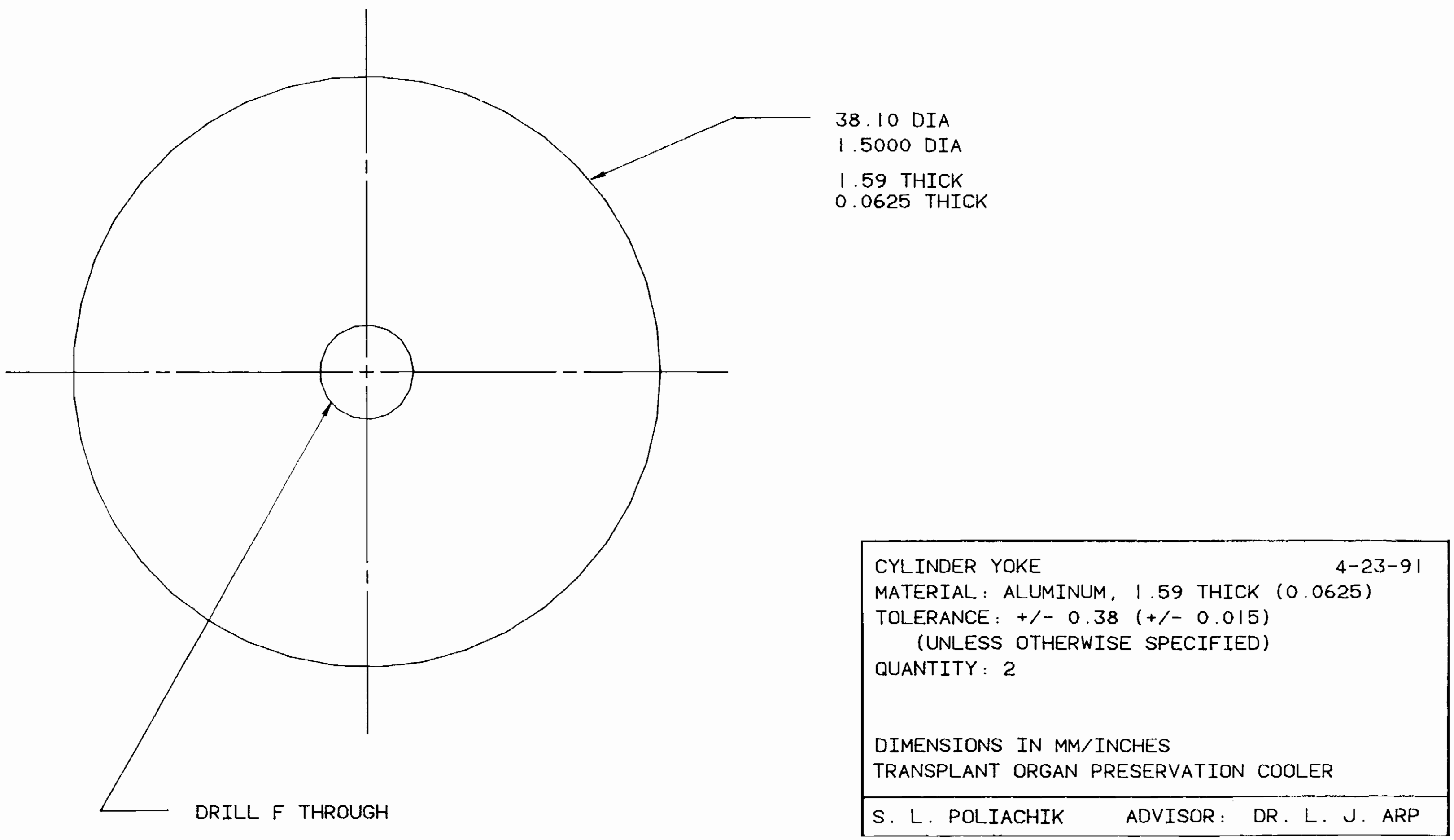


Figure 15. Pump Apparatus: Cylinder Yoke

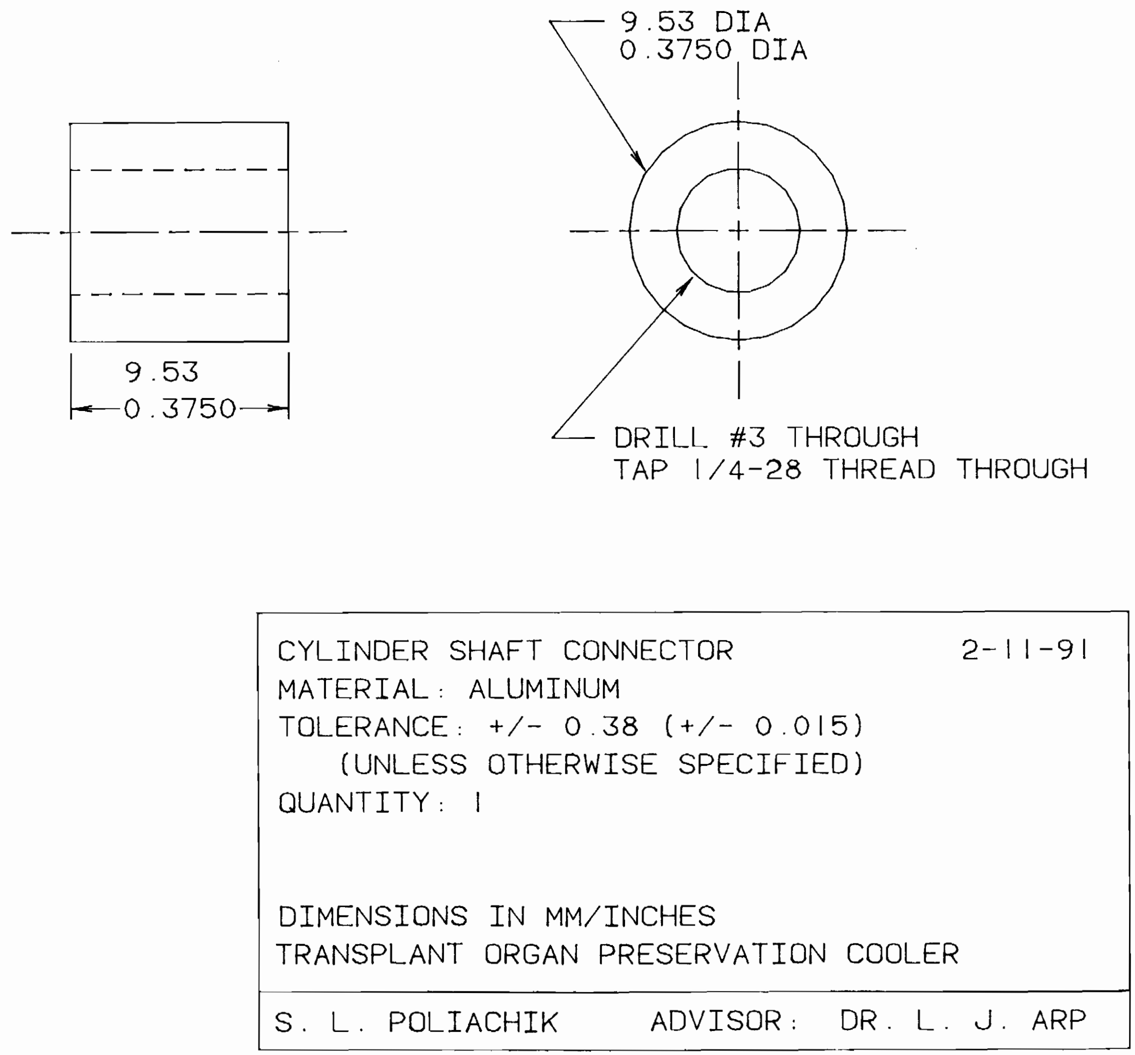


Figure 16. Pump Apparatus: Cylinder Shaft Connector

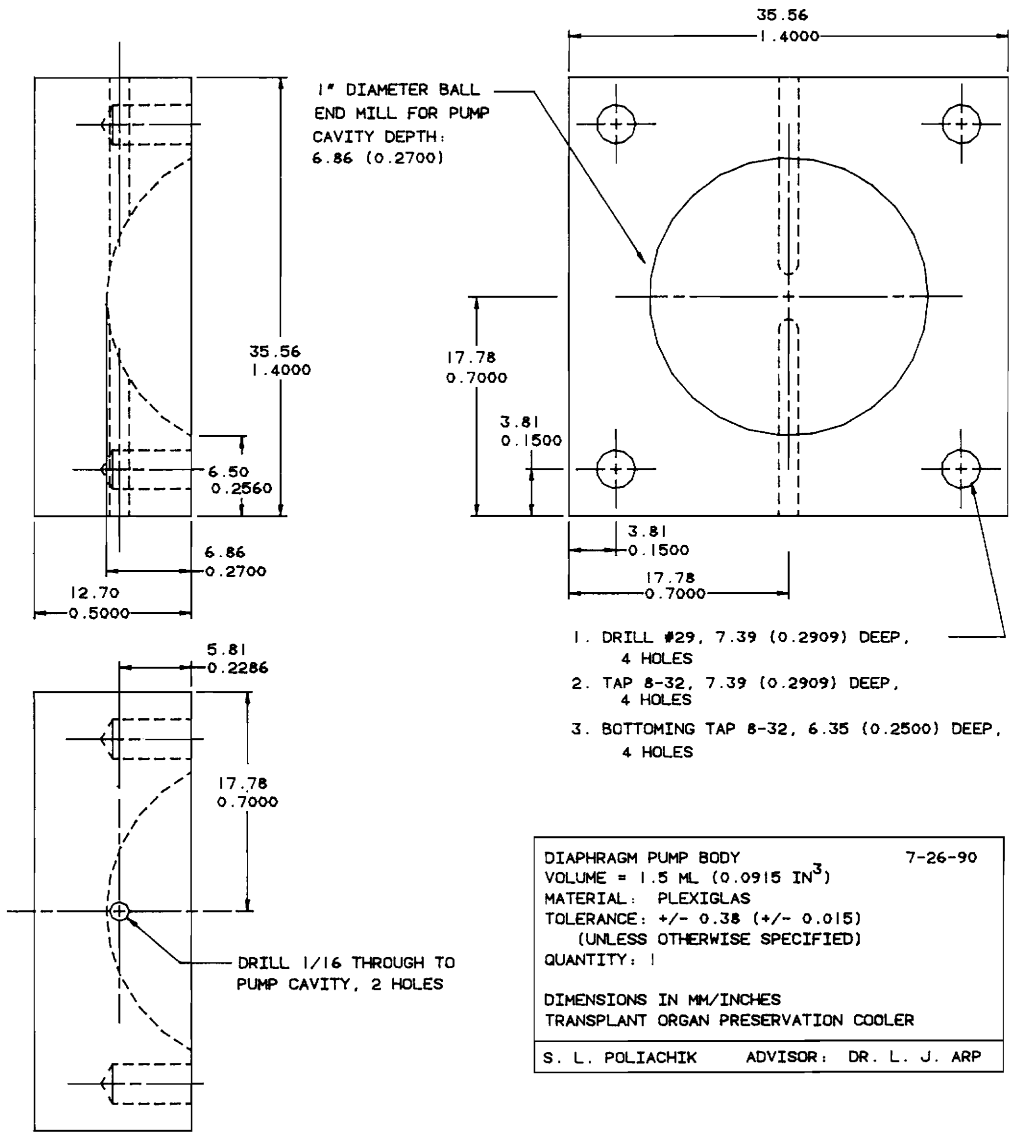


Figure 17. Pump Apparatus: Diaphragm Pump Body

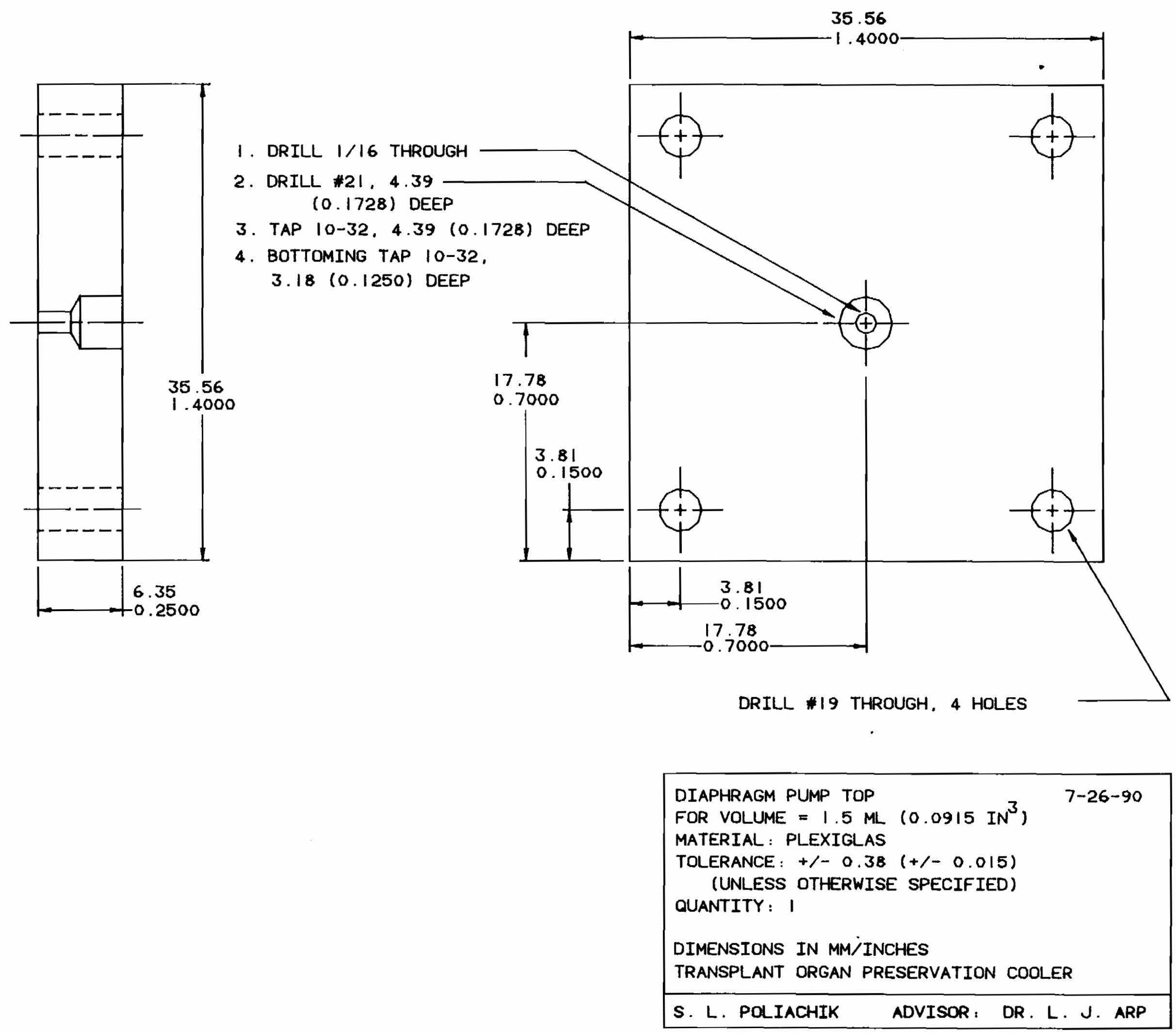


Figure 18. Pump Apparatus: Diaphragm Pump Lid

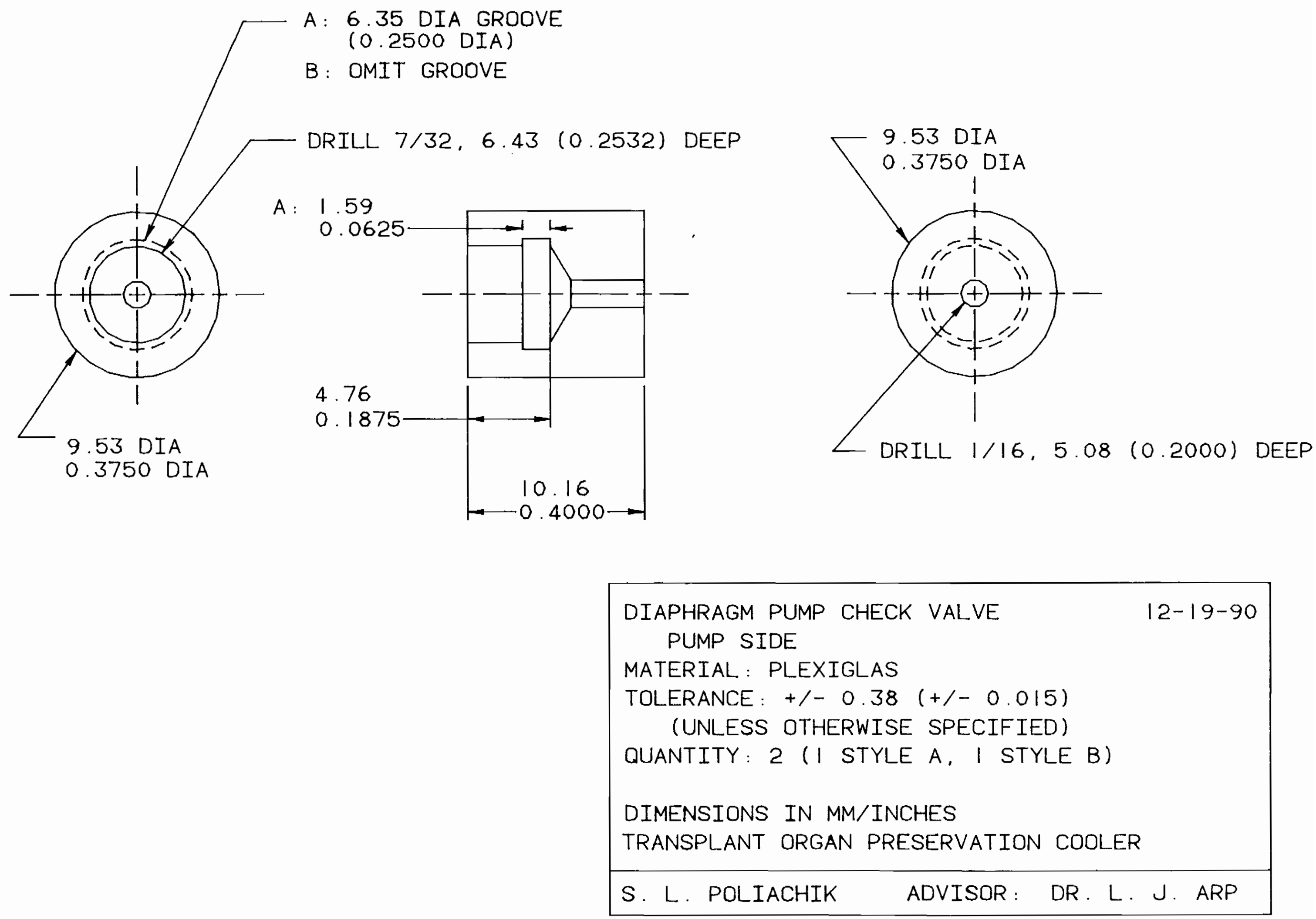


Figure 19. Pump Apparatus: Diaphragm Pump Check Valve, Pump Side

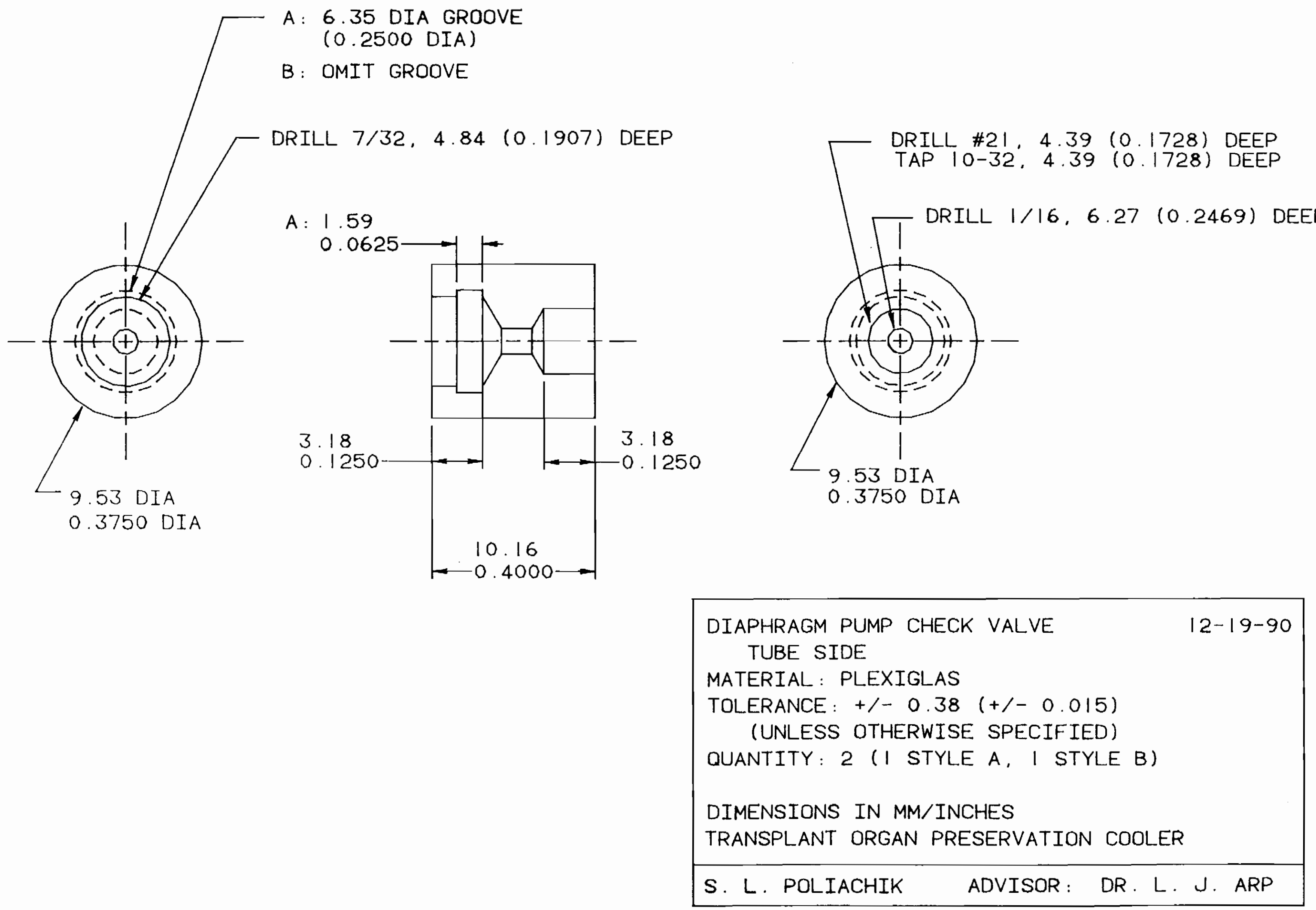


Figure 20. Pump Apparatus: Diaphragm Pump Check Valve, Tube Side

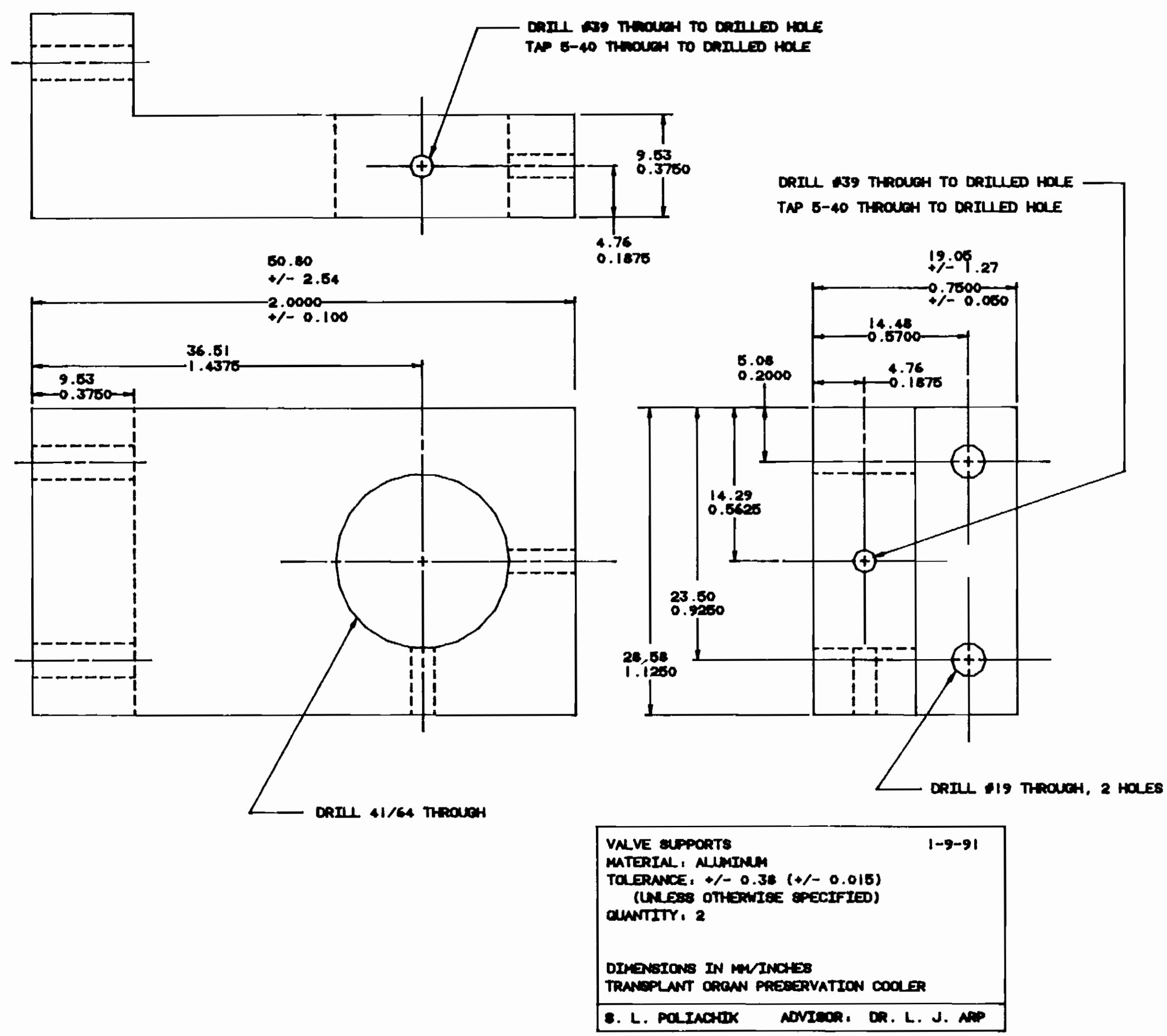


Figure 21. Pump Apparatus: Oxygen Valve Support

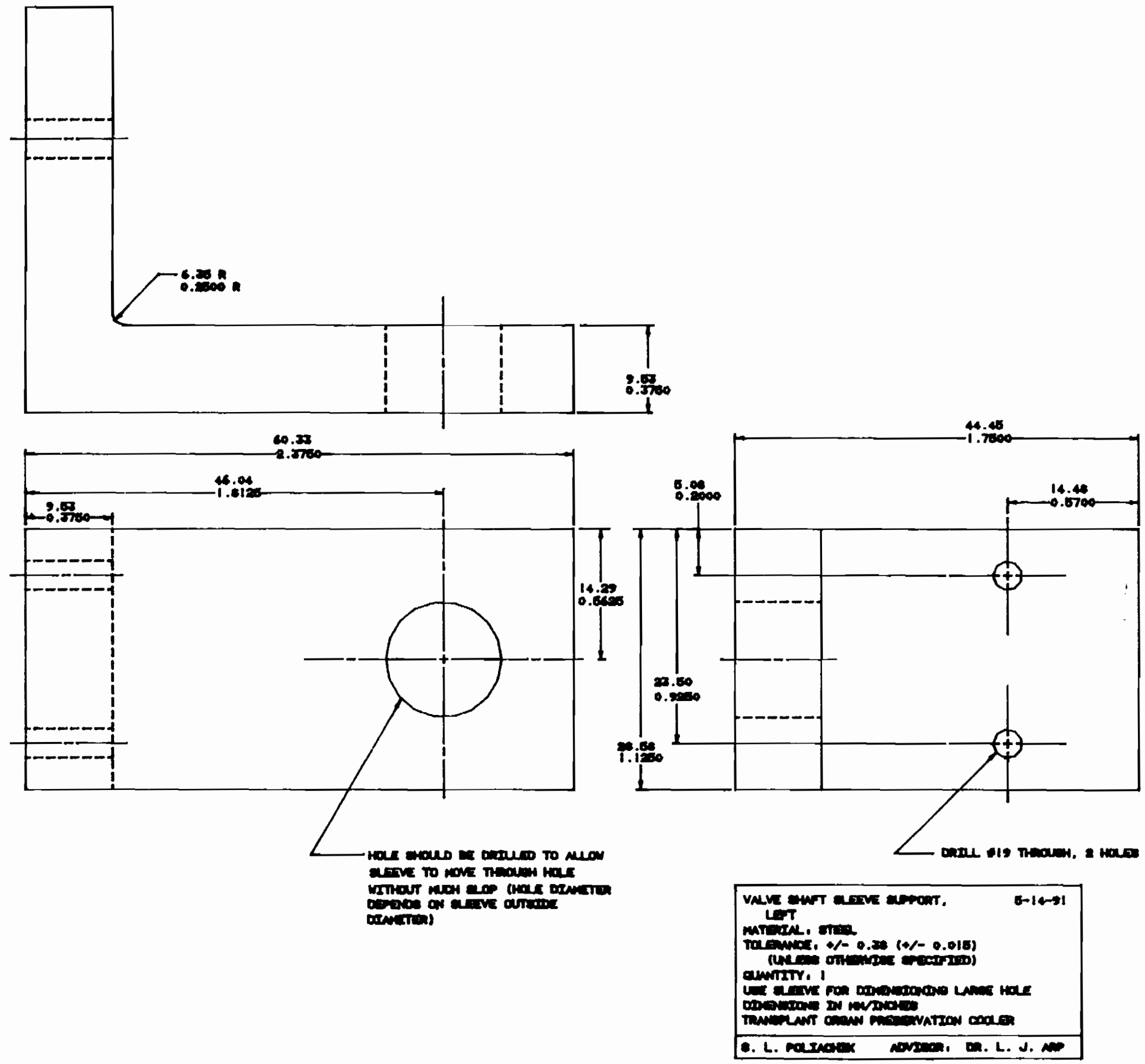


Figure 22. Pump Apparatus: Valve Shaft Sleeve Support, Left

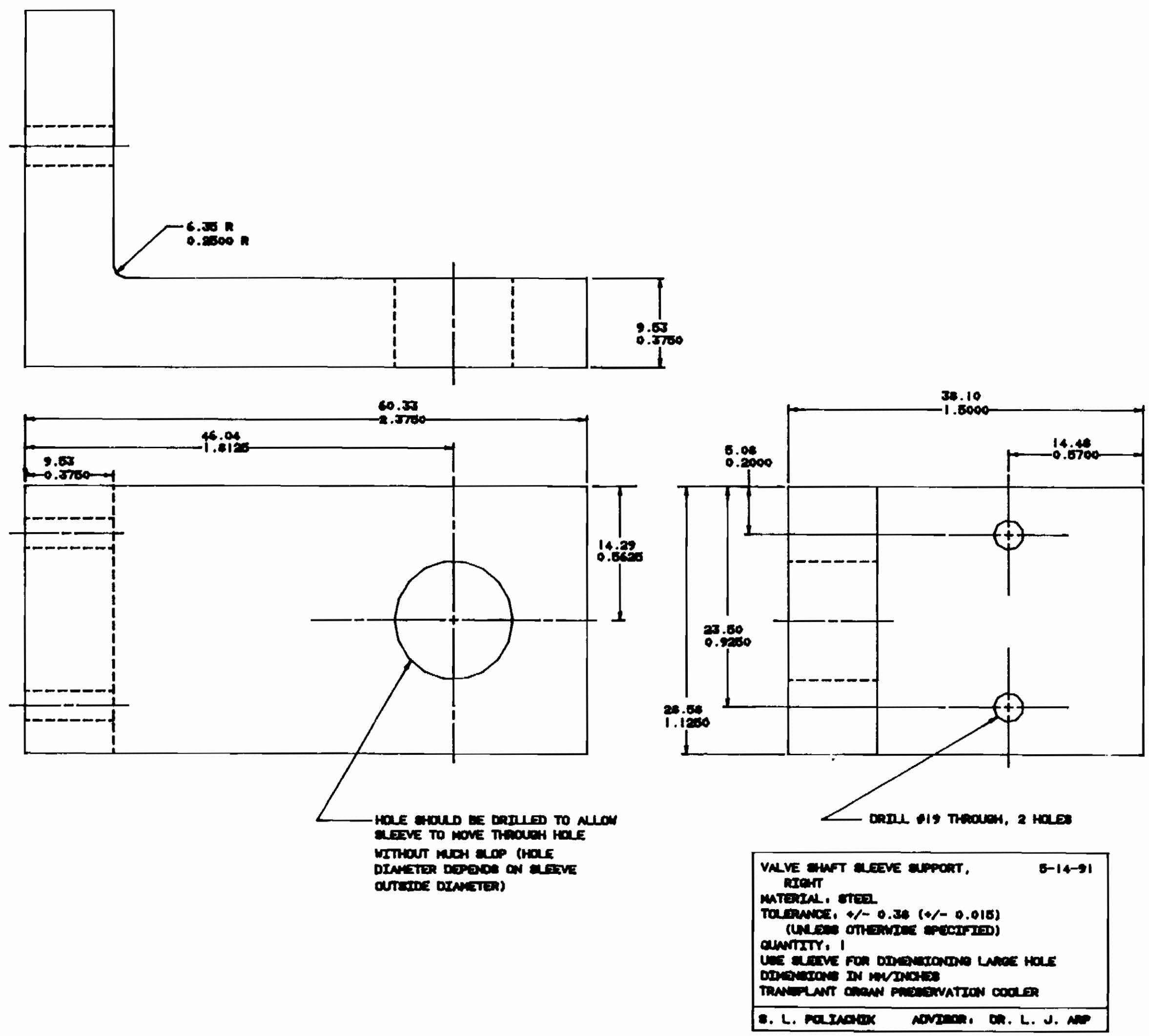


Figure 23. Pump Apparatus: Valve Shaft Sleeve Support, Right

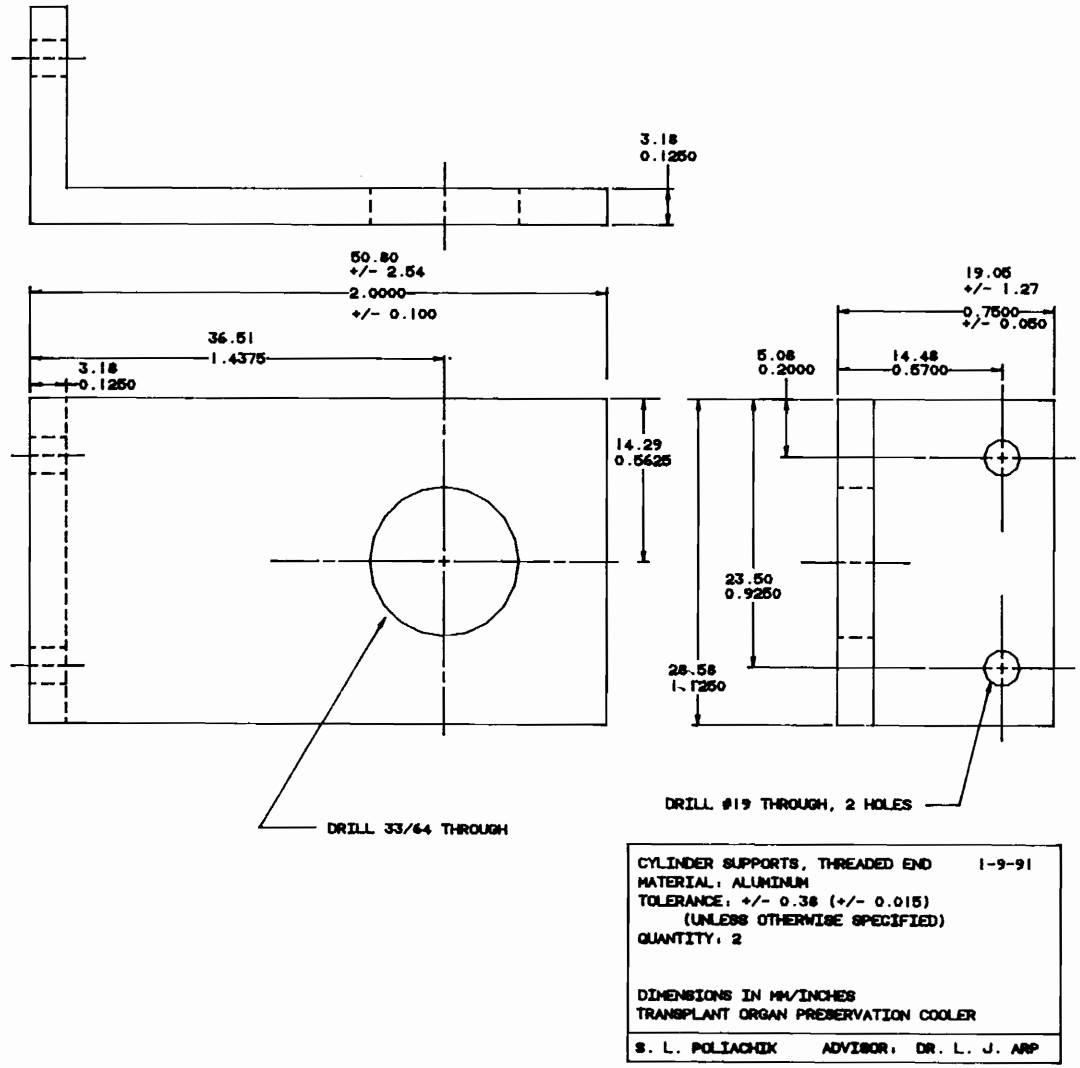


Figure 24. Pump Apparatus: Cylinder Support, Threaded End

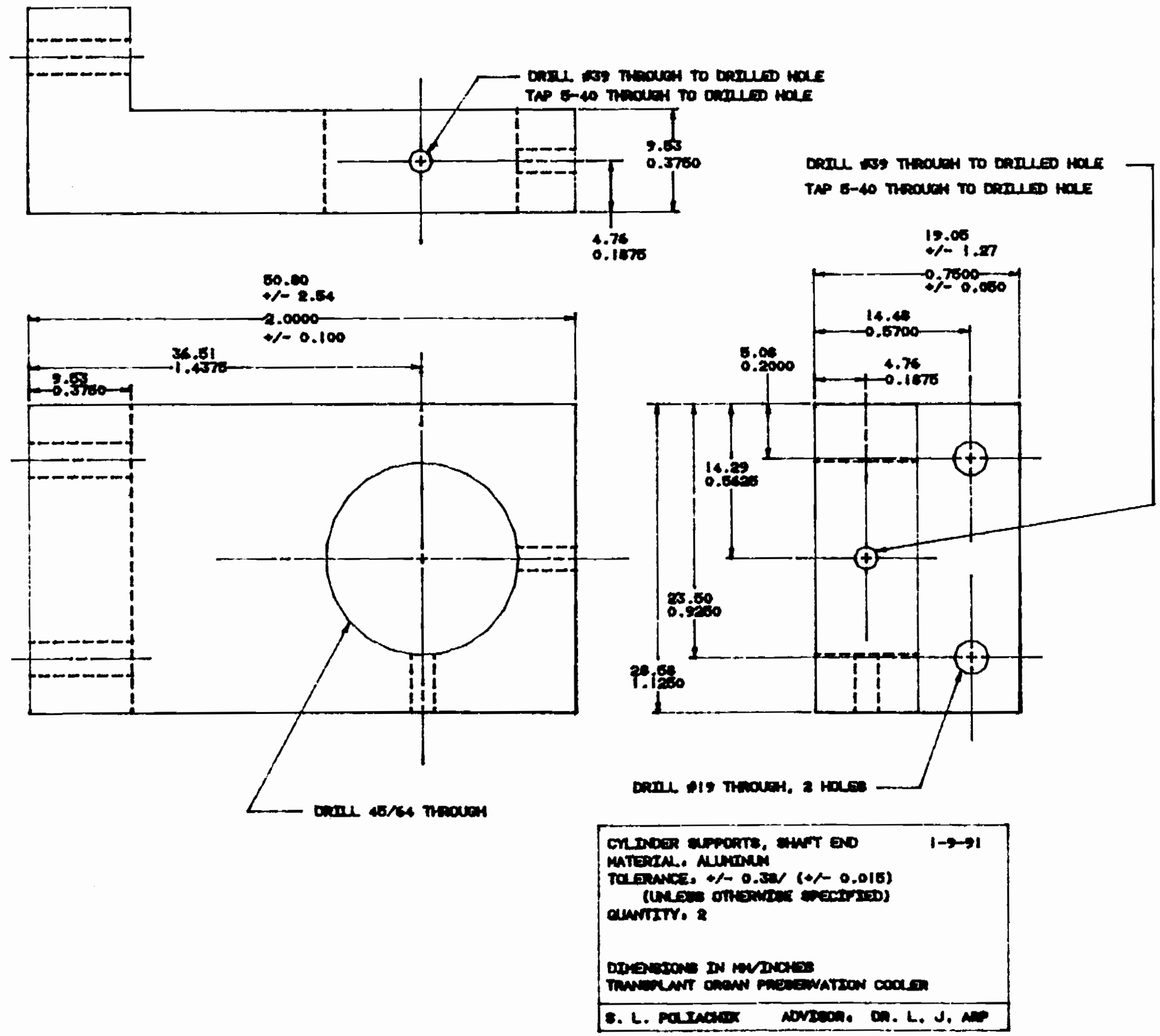


Figure 25. Pump Apparatus: Cylinder Support, Shaft End

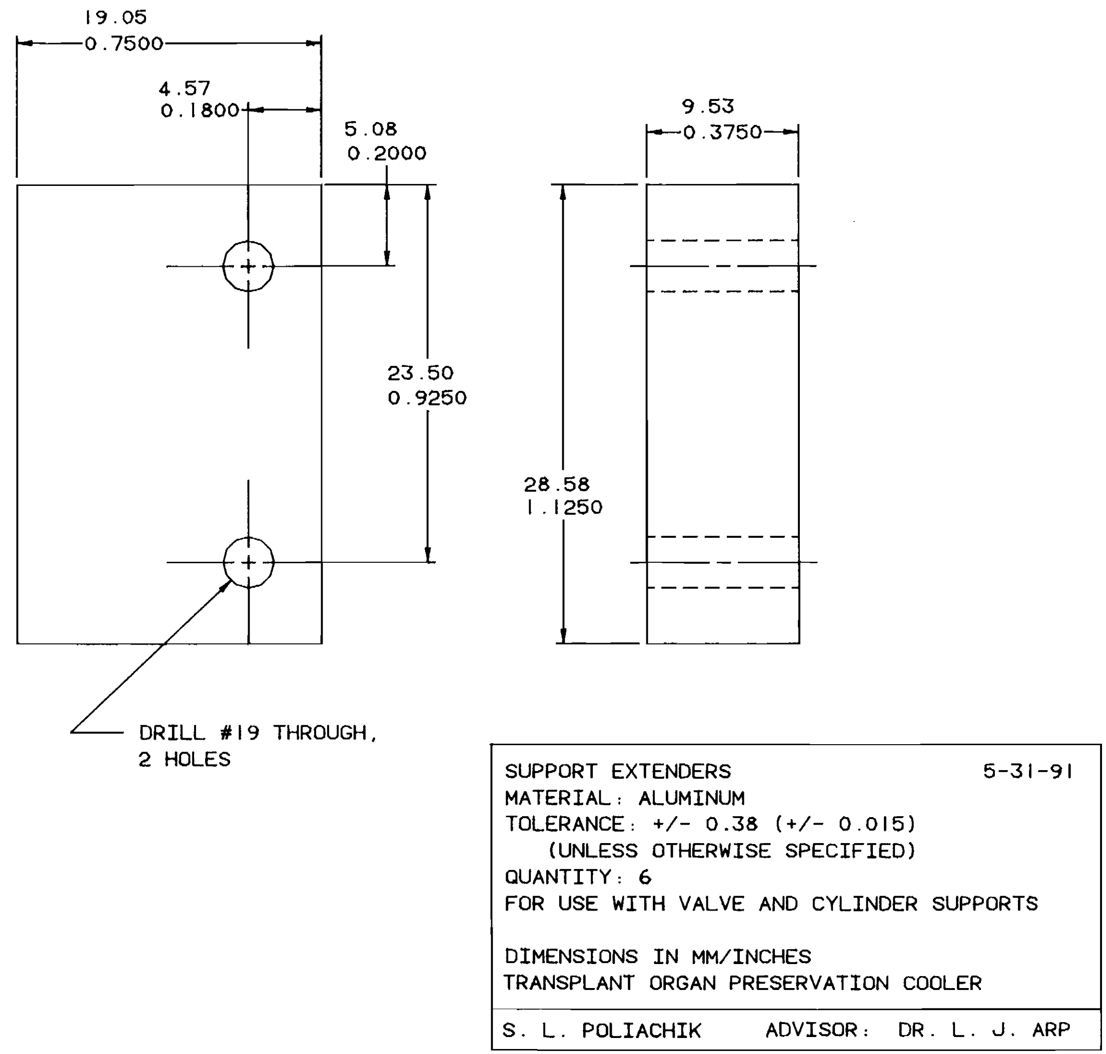


Figure 26. Pump Apparatus: Support Extender

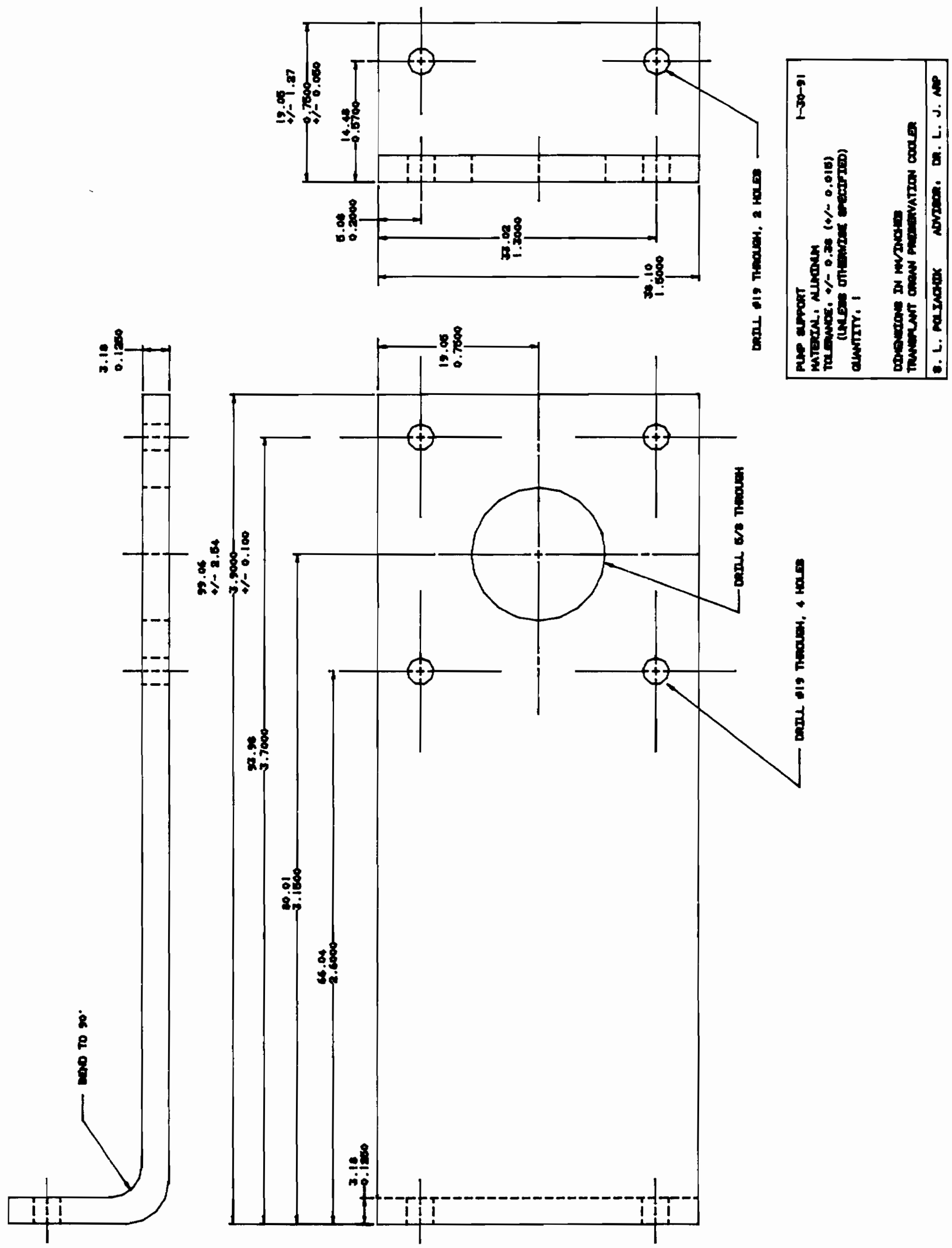


Figure 27. Pump Apparatus: Pump Support

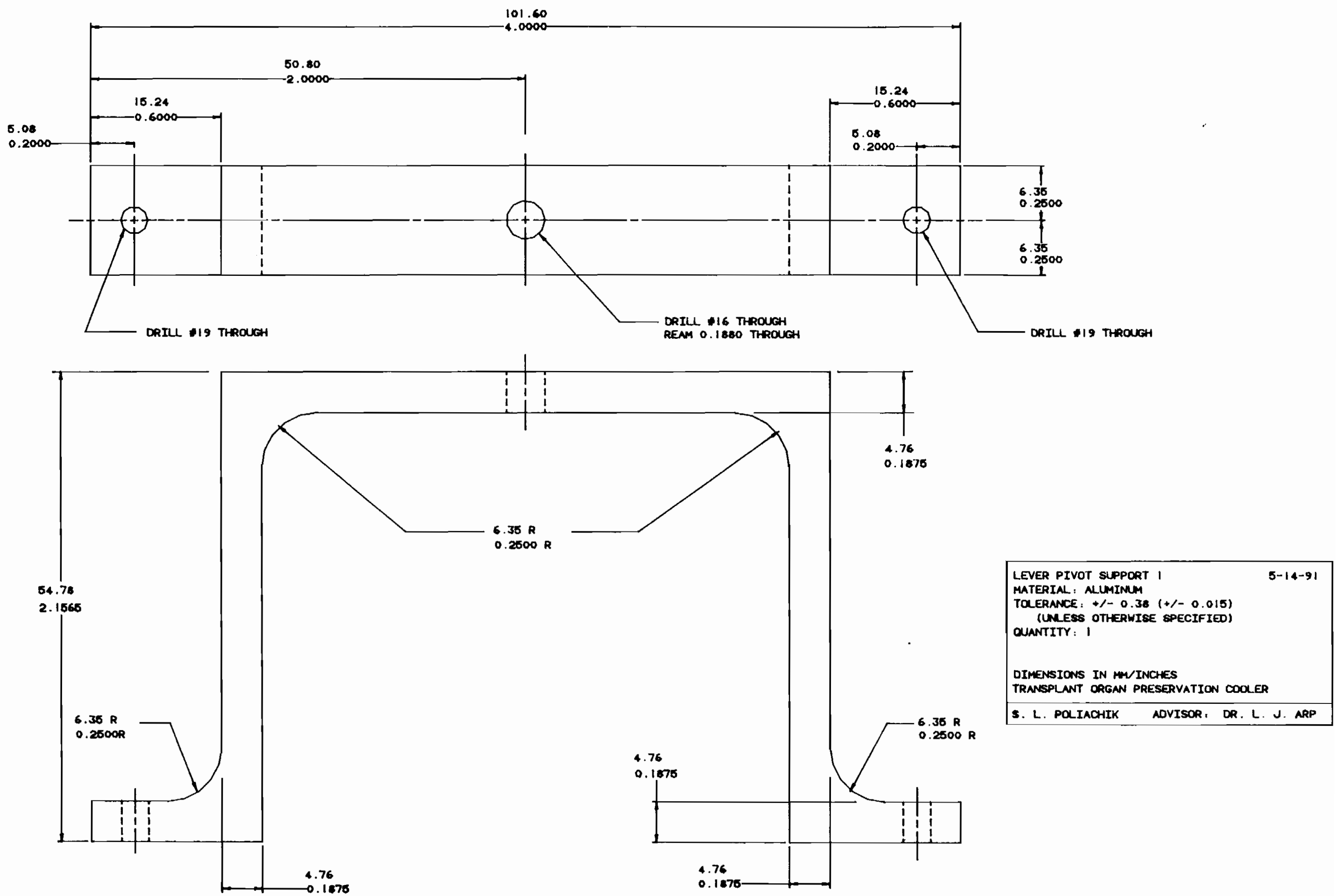


Figure 28. Pump Apparatus: Lever Arm Pivot Rod Support, 1

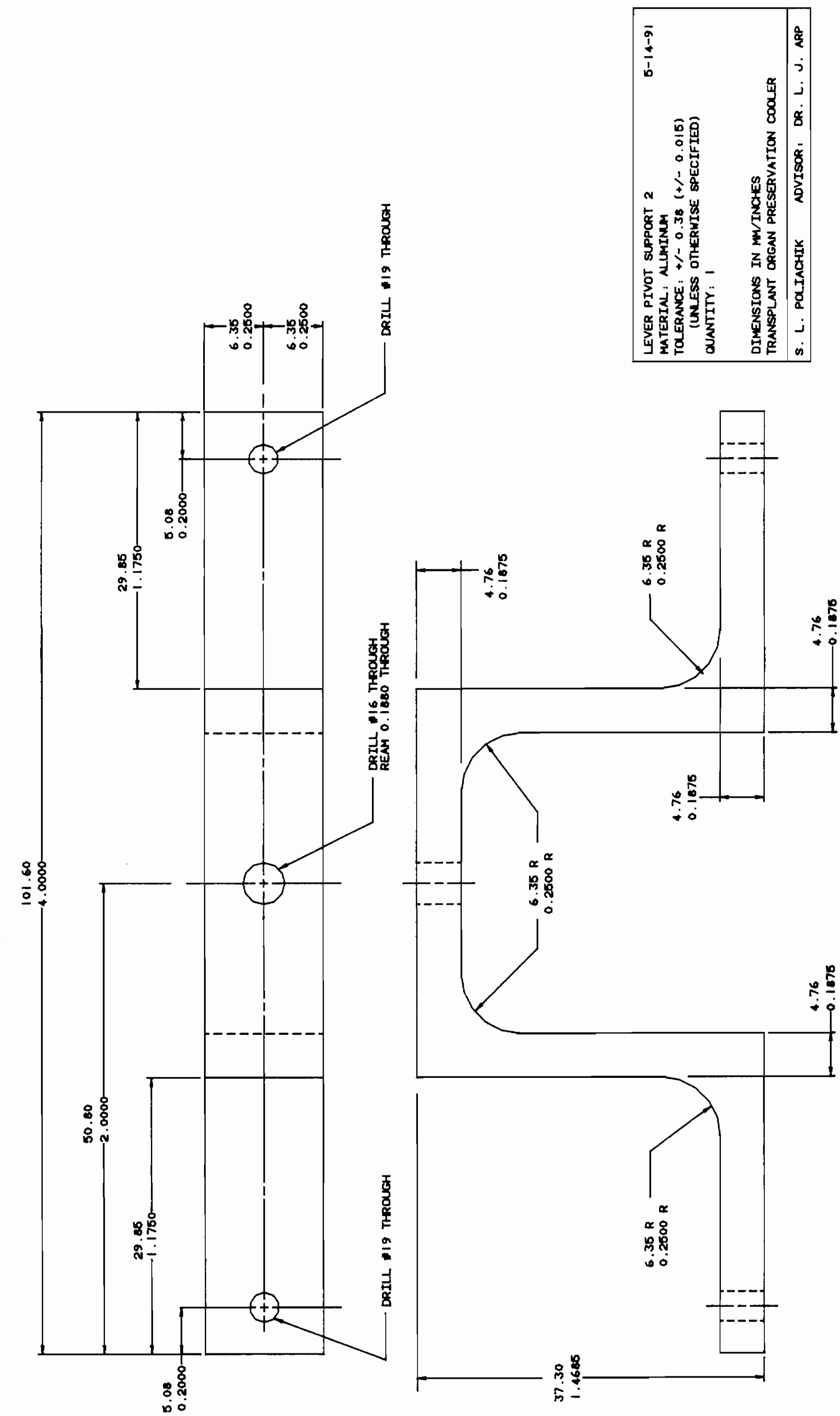


Figure 29. Pump Apparatus: Lever Arm Pivot Rod Support, 2

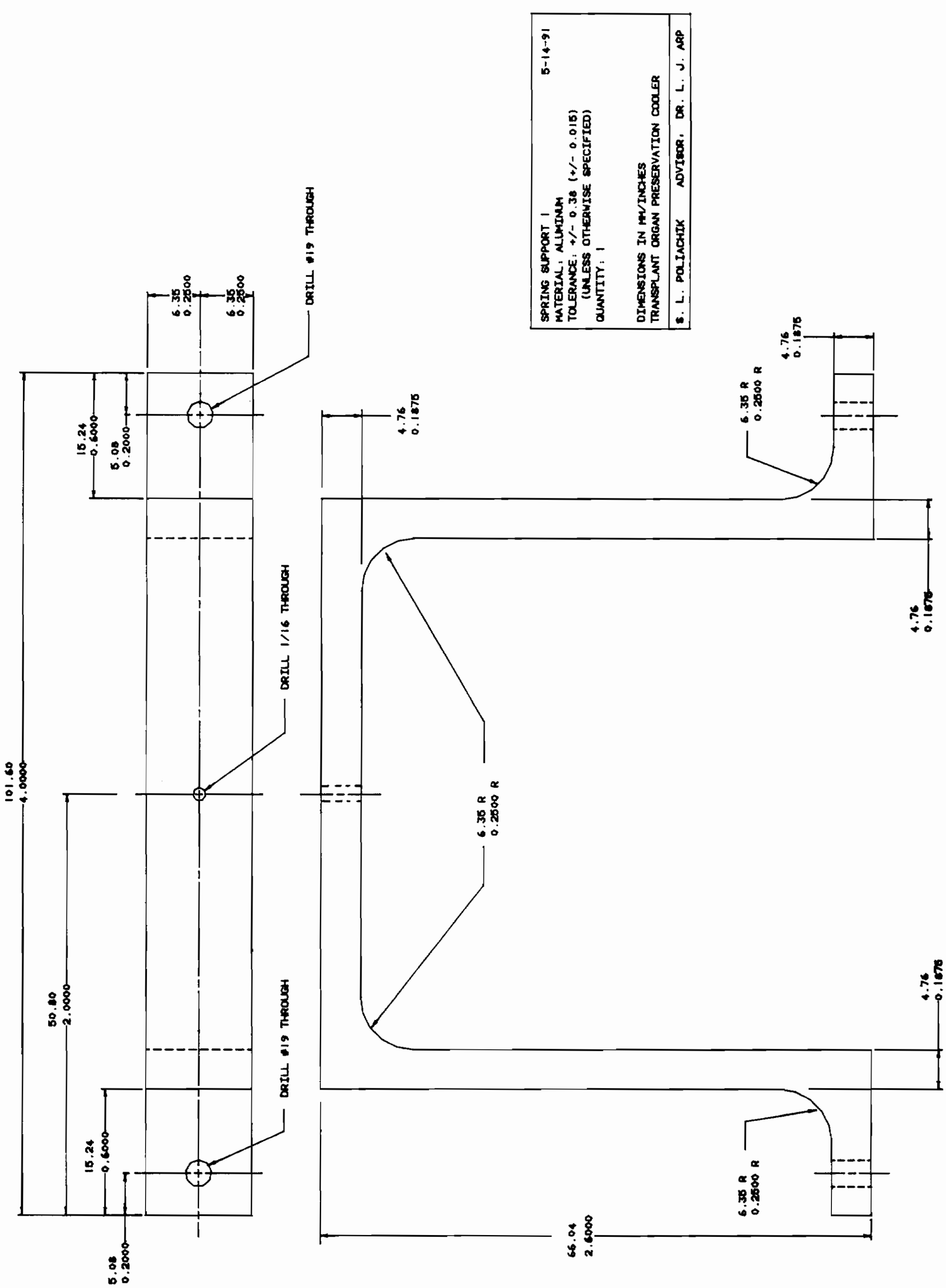


Figure 30. Pump Apparatus: Spring Support, 1

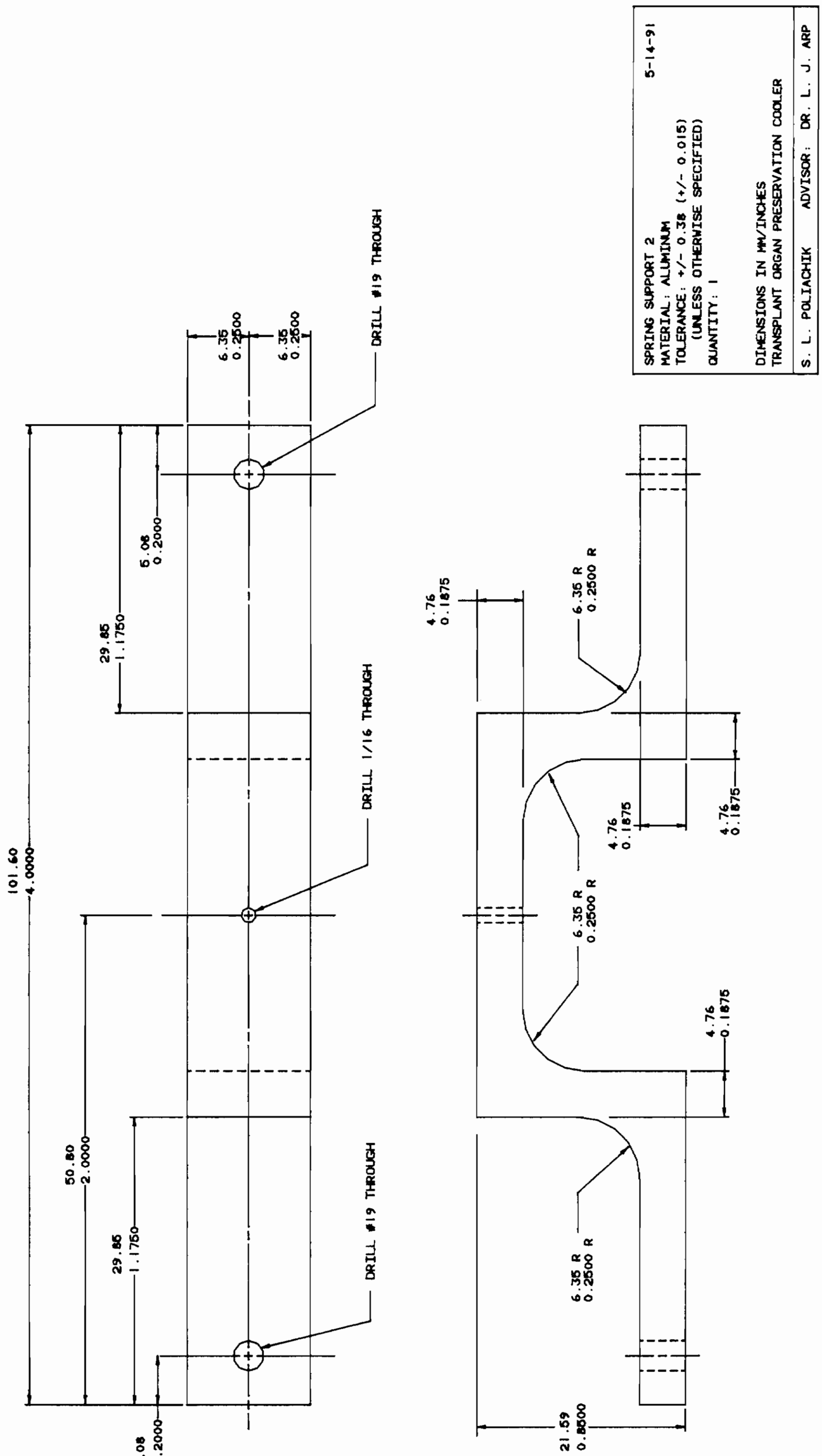


Figure 31. Pump Apparatus: Spring Support, 2

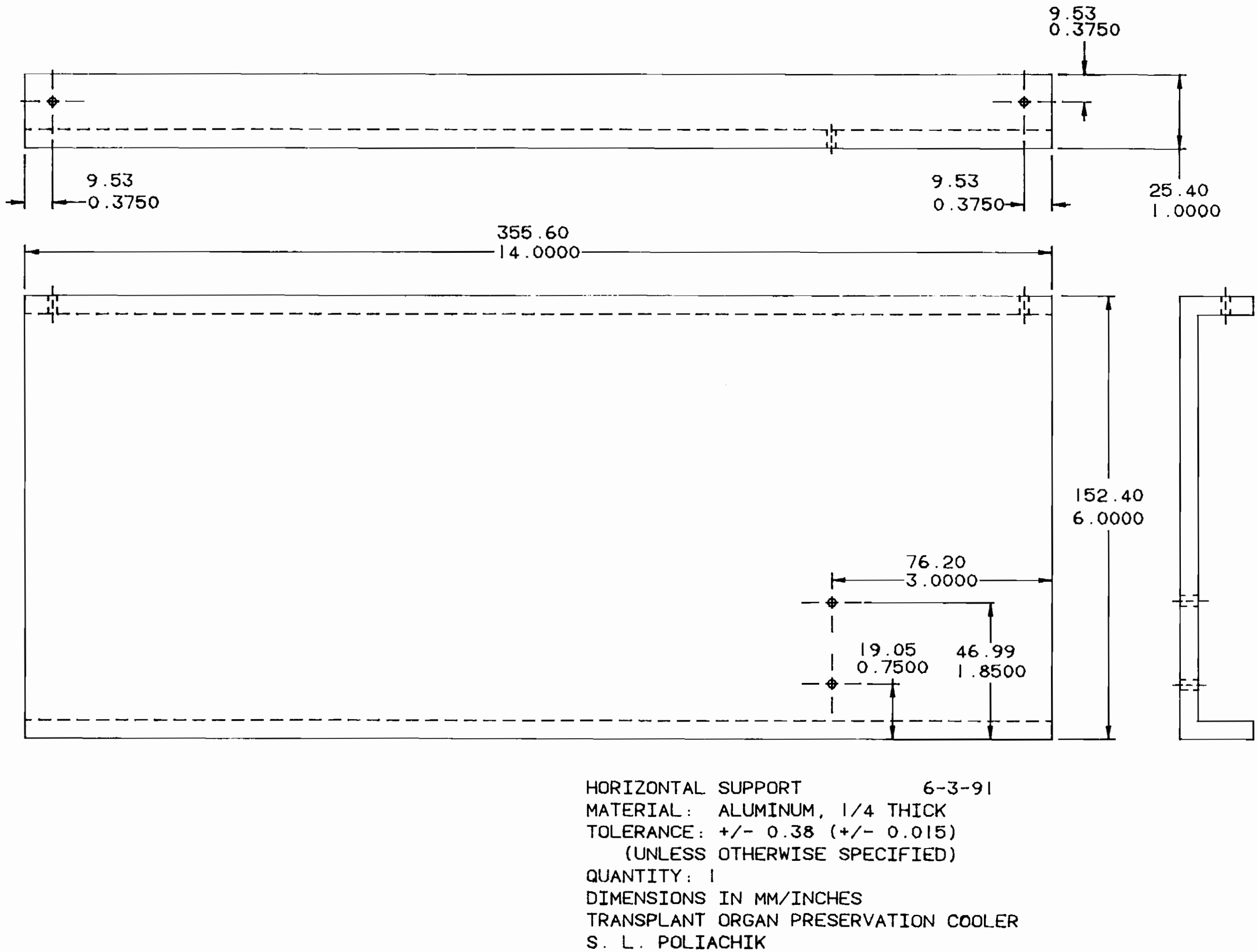


Figure 32. Pump Apparatus: Horizontal Support

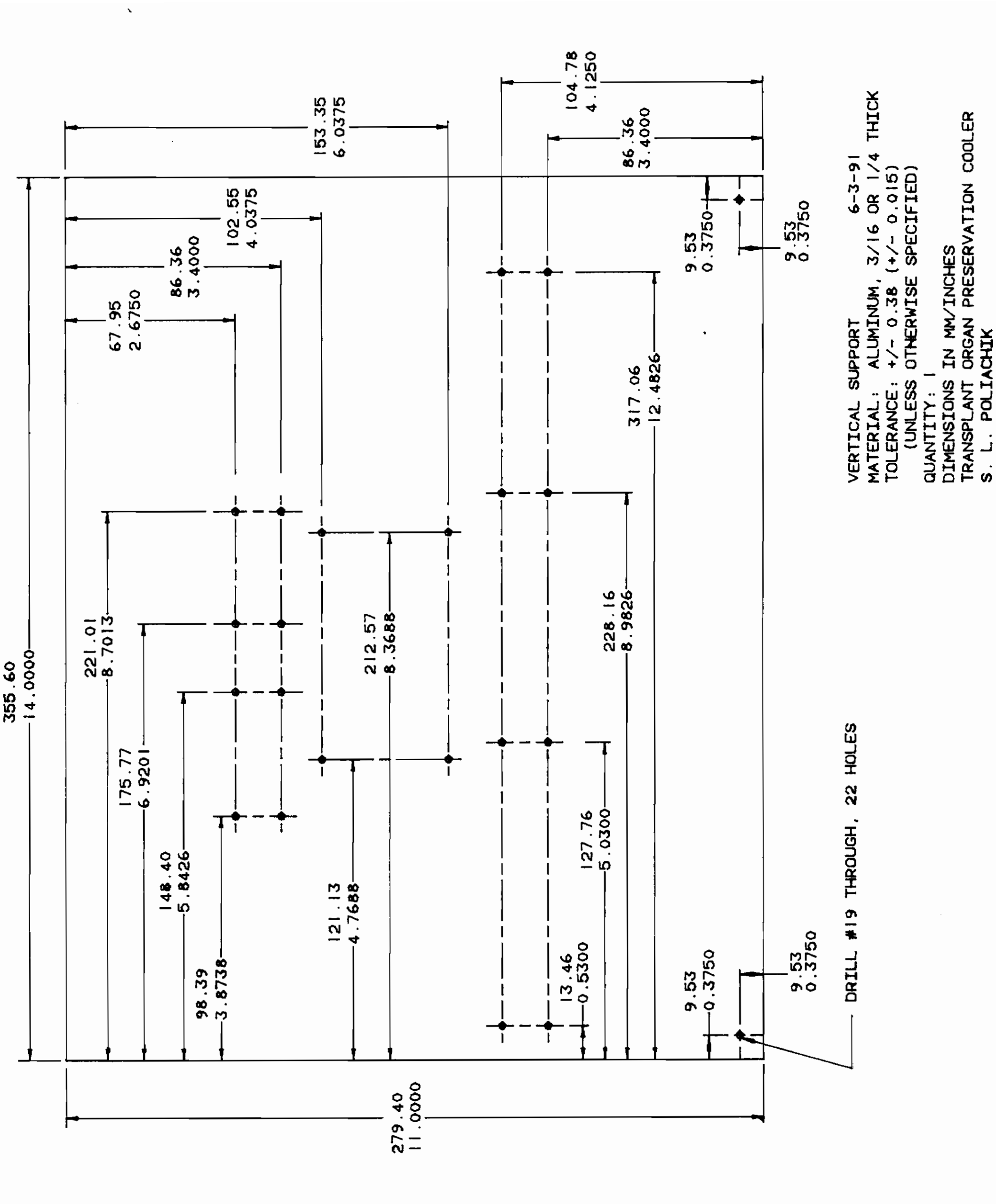


Figure 33. Pump Apparatus: Vertical Support

Appendix B. Temperature Control Parts

Table 5. Parts List–Temperature Control, Option One

Quantity	Part	Figure No.
4	Cooling & Vent Butterfly Valve Casing	34
4	Cooling & Vent Butterfly Valve Seat	35
4	Cooling & Vent Butterfly Half Valve Plate	36
2	Cooling & Vent Butterfly Valve Tubing Connection	37
3	10-32 to 1/8″ OD Tubing Fitting, Swagelok B-200-6-1	--
1	Cooling & Vent Butterfly Valve Shaft Connection	38
1	Cooling & Vent Butterfly Valve Shaft/Link Connection	39
2	Cooling & Vent Butterfly Valve Shaft, 1/16″Diameter	--
6	2-56 Set Screws, 1/4″	--
1 each	Oxygen Exit Chamber Walls	40
1	Oxygen Exit Chamber, Entrance Wall	41
1	Oxygen Exit Chamber, Exit Wall	42
1	1/8″ OD Fractional Tube Tee, Swagelok B-200-3	--
1 each	Linkages to Bimetallic Coil	43
2	6-32 Screws, 3/8″; nut	--
1	Bimetallic Coil	--
1	Pin for Bimetallic Coil Loop; Washers;Snap Ring	--
1 each	Bimetallic Coil Box	44
1	Bimetallic Coil Support	45
2	6-32 Screw, 3/8″	--
2.5m (8.2 ft)	1/8″ OD Stainless Steel Tubing	--

Table 6. Parts List–Temperature Control, Option Two

Quantity	Part	Figure No.
2	10-32 to 1/8″ OD Tubing Fitting Swagelok B-200-3	-- --
4.6m (15 ft)	1/8″ OD Stainless Steel Tubing	--

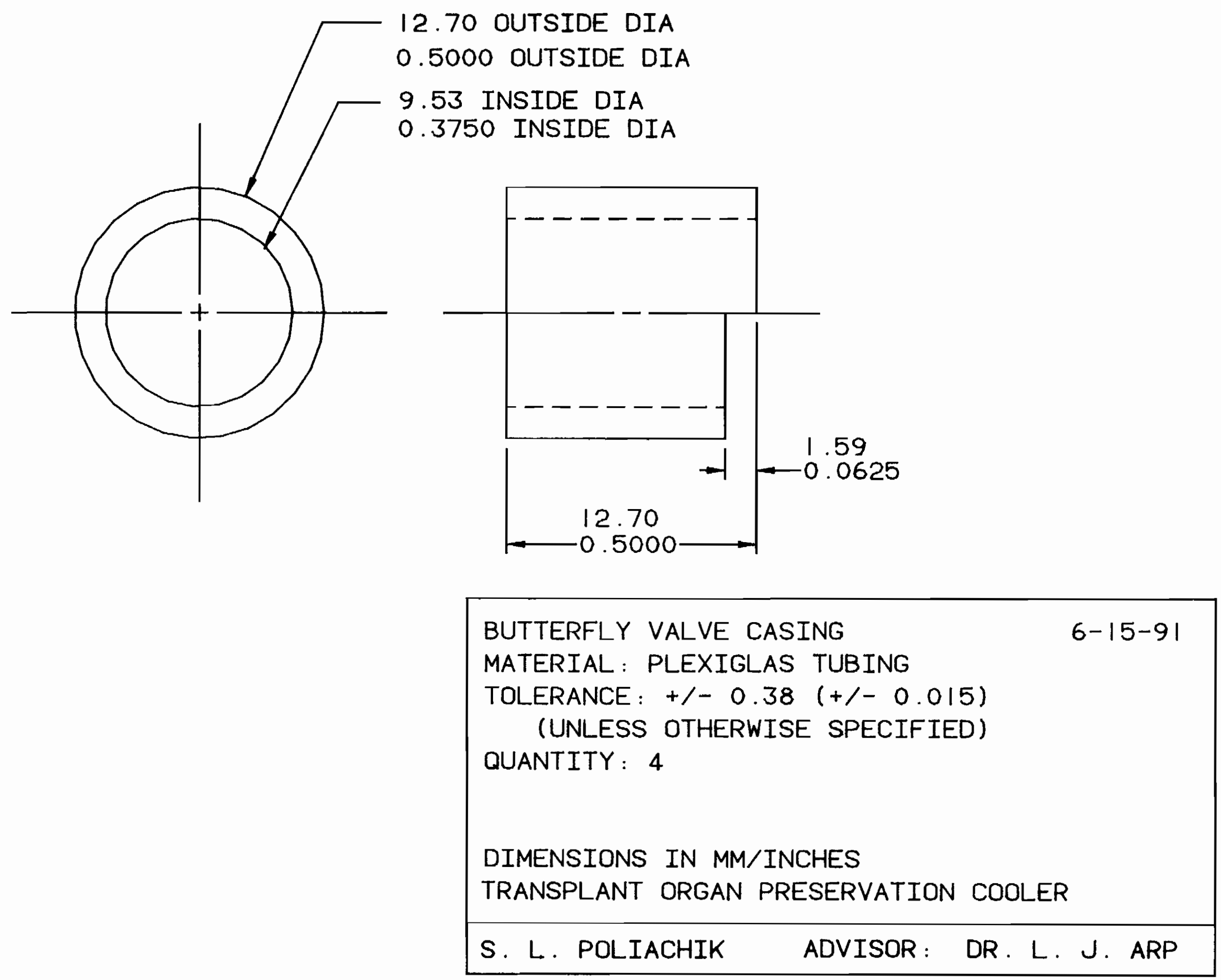
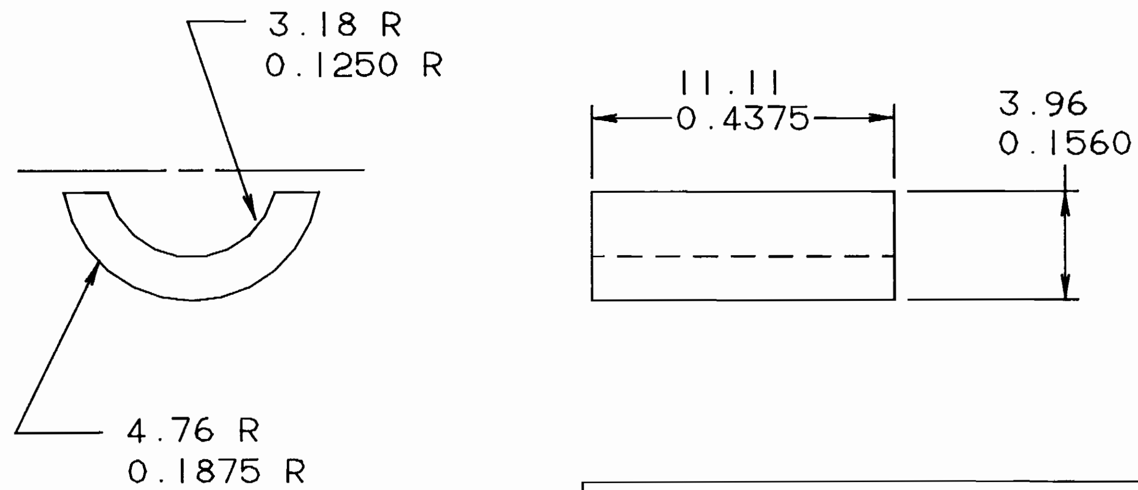


Figure 34. Temperature Control: Cooling and Vent Butterfly Valve Casing



BUTTERFLY VALVE CASING: VALVE SEAT 6-15-91
MATERIAL: PLEXIGLAS
TOLERANCE: +/- 0.38 (+/- 0.015)
(UNLESS OTHERWISE SPECIFIED)
QUANTITY: 4

DIMENSIONS IN MM/INCHES
TRANSPLANT ORGAN PRESERVATION COOLER

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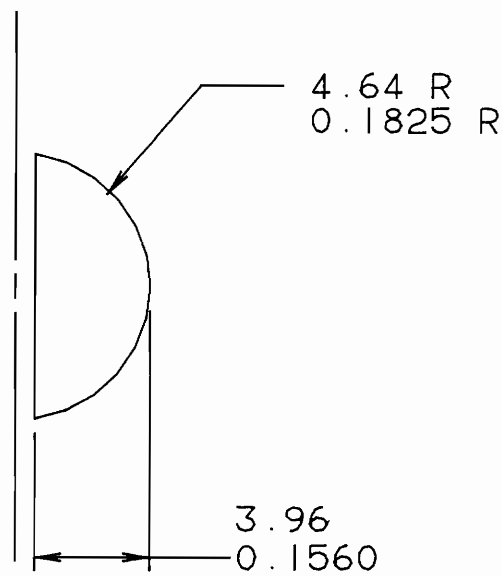
Figure 35. Temperature Control: Cooling and Vent Butterfly Valve Seat



BUTTERFLY VALVE PLATE 6-15-91
MATERIAL: BRASS, 1.59 (0.0625) THICK
TOLERANCE: +/- 0.38 (+/- 0.015)
(UNLESS OTHERWISE SPECIFIED)
QUANTITY: 4

DIMENSIONS IN MM/INCHES
TRANSPLANT ORGAN PRESERVATION COOLER

S. L. POLIACHIK ADVISOR: DR. L. J. ARP

Figure 36. Temperature Control: Cooling and Vent Butterfly Valve Plate Half

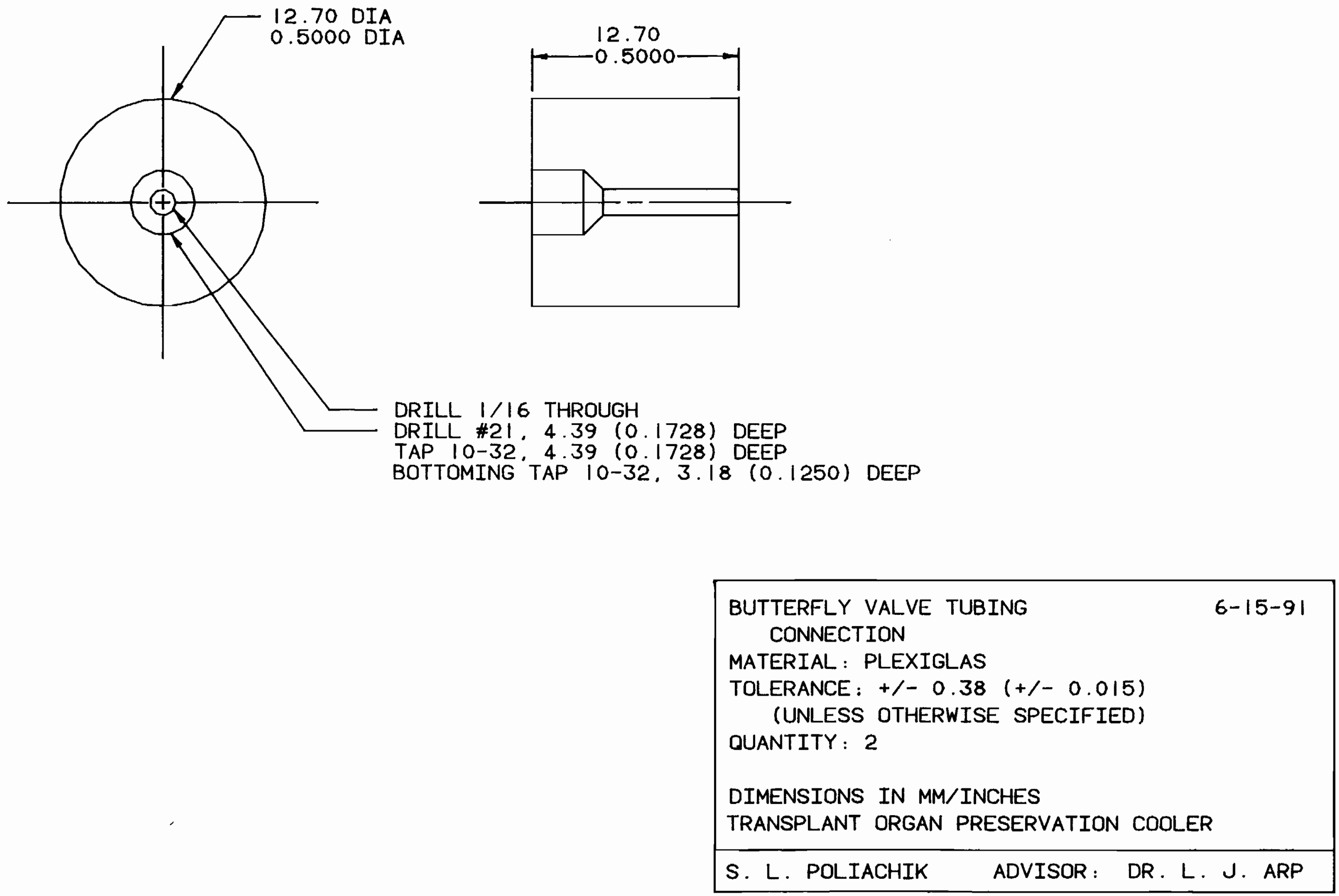


Figure 37. Temperature Control: Cooling and Vent Butterfly Valve Tubing Connection

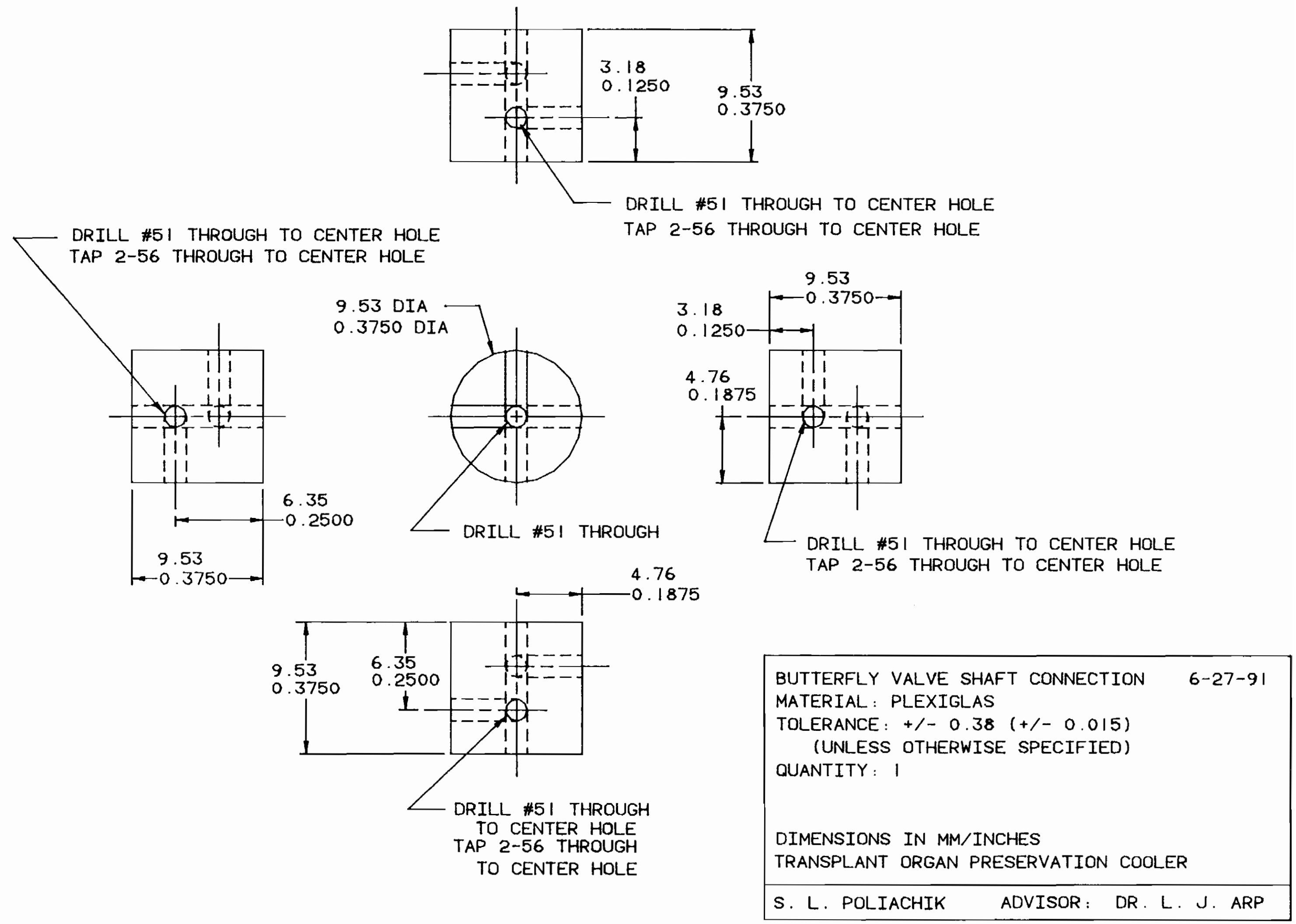


Figure 38. Temperature Control: Cooling and Vent Butterfly Valve Shaft Connection

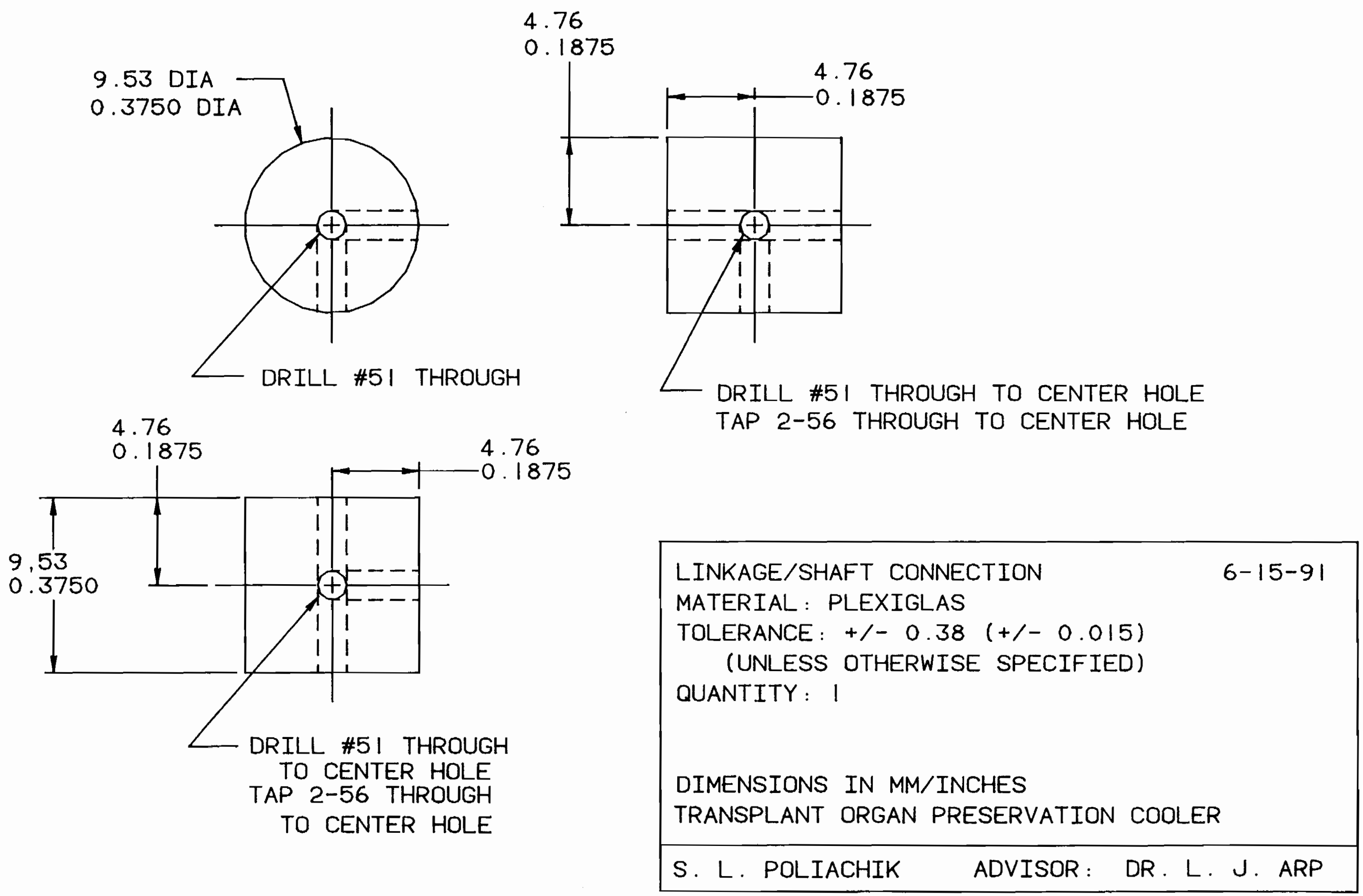


Figure 39. Temperature Control: Cooling Butterfly Valve Shaft/Linkage Connection

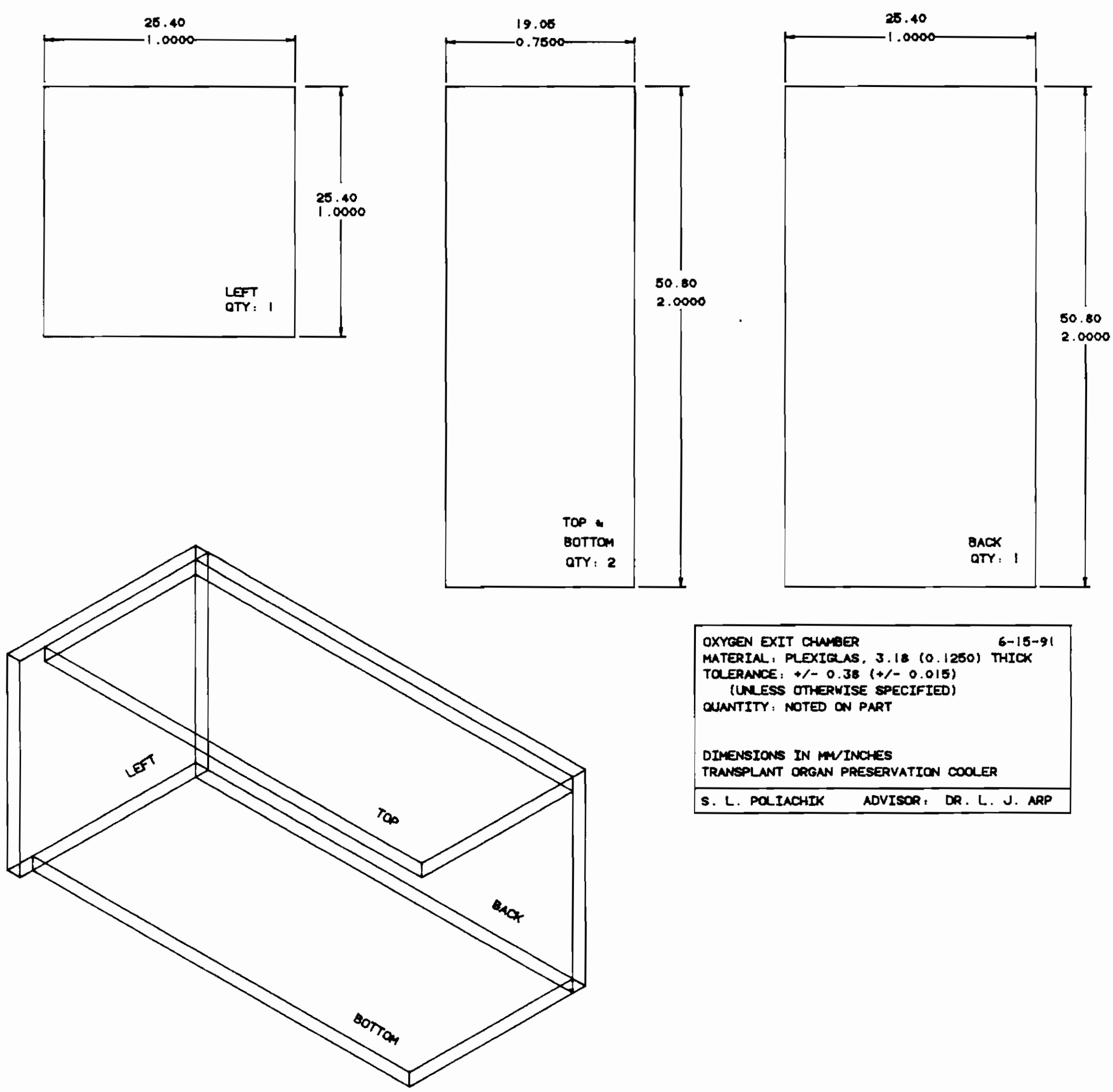
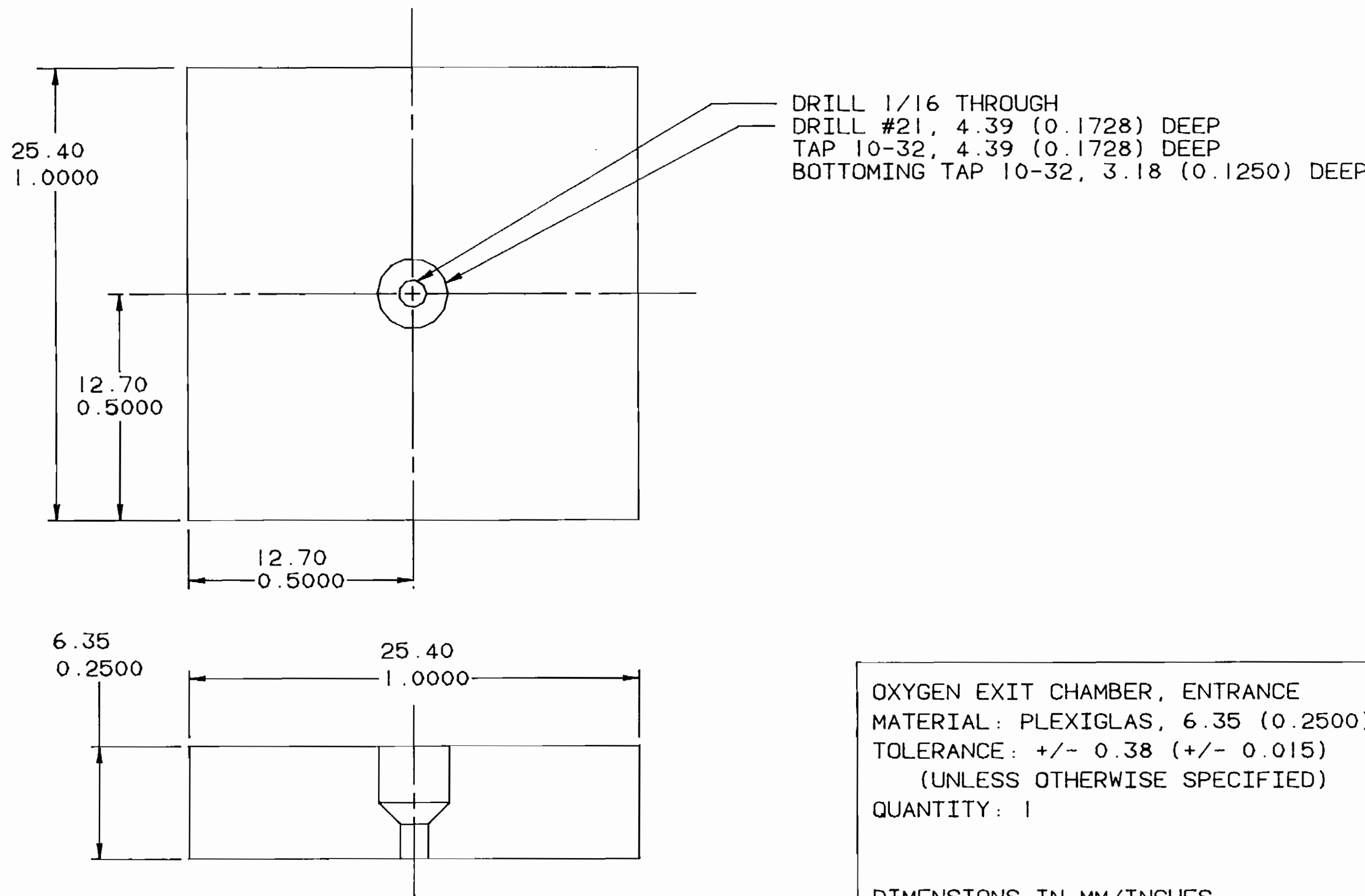


Figure 40. Temperature Control: Oxygen Exit Chamber Walls



OXYGEN EXIT CHAMBER, ENTRANCE 6-15-91
MATERIAL: PLEXIGLAS, 6.35 (0.2500) THICK
TOLERANCE: +/- 0.38 (+/- 0.015)
(UNLESS OTHERWISE SPECIFIED)
QUANTITY: 1

DIMENSIONS IN MM/INCHES
TRANSPLANT ORGAN PRESERVATION COOLER

S. L. POLIACHIK ADVISOR: DR. L. J. ARP

Figure 41. Temperature Control: Oxygen Exit Chamber, Entrance Wall

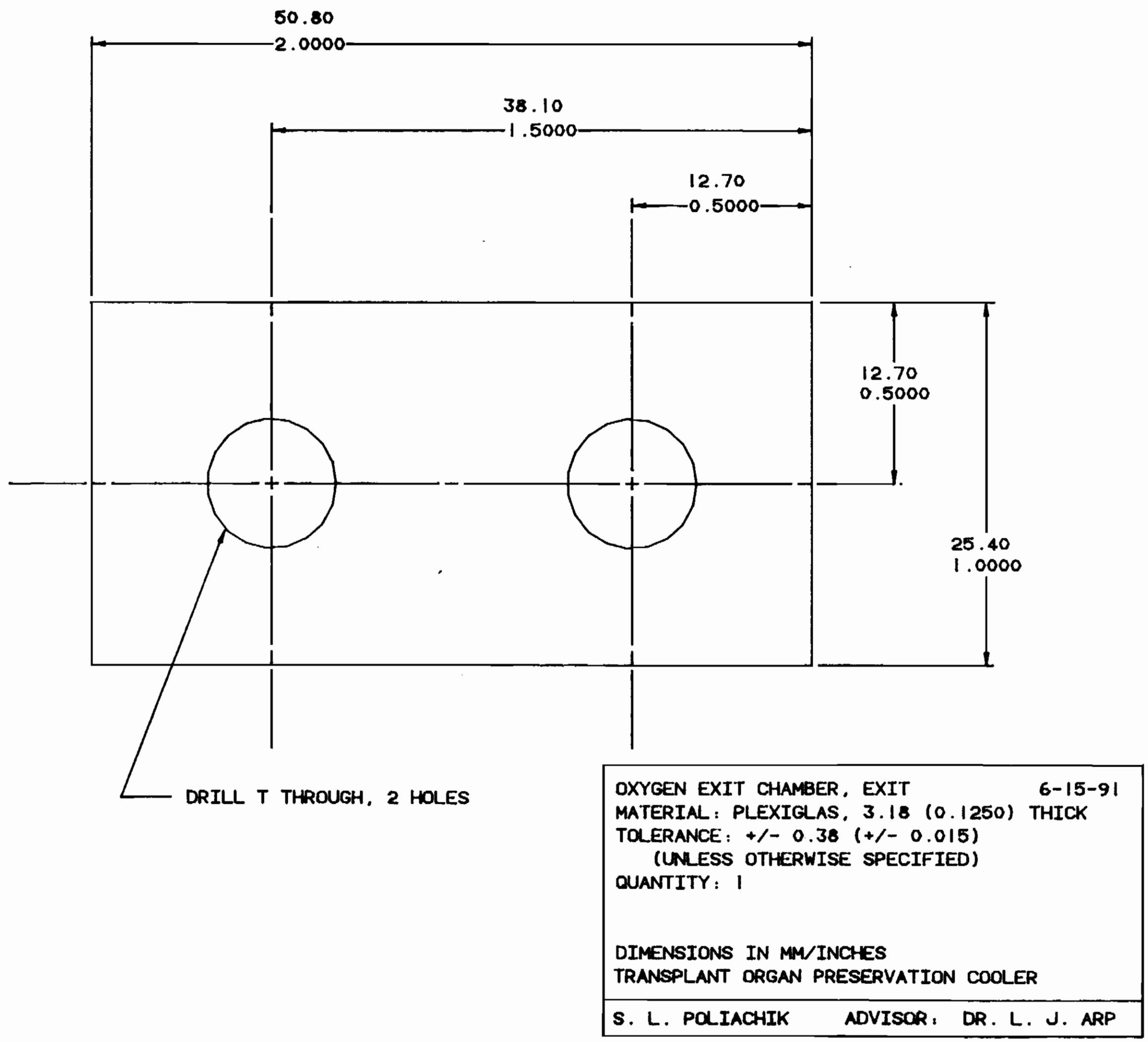


Figure 42. Temperature Control: Oxygen Exit Chamber, Exit Wall

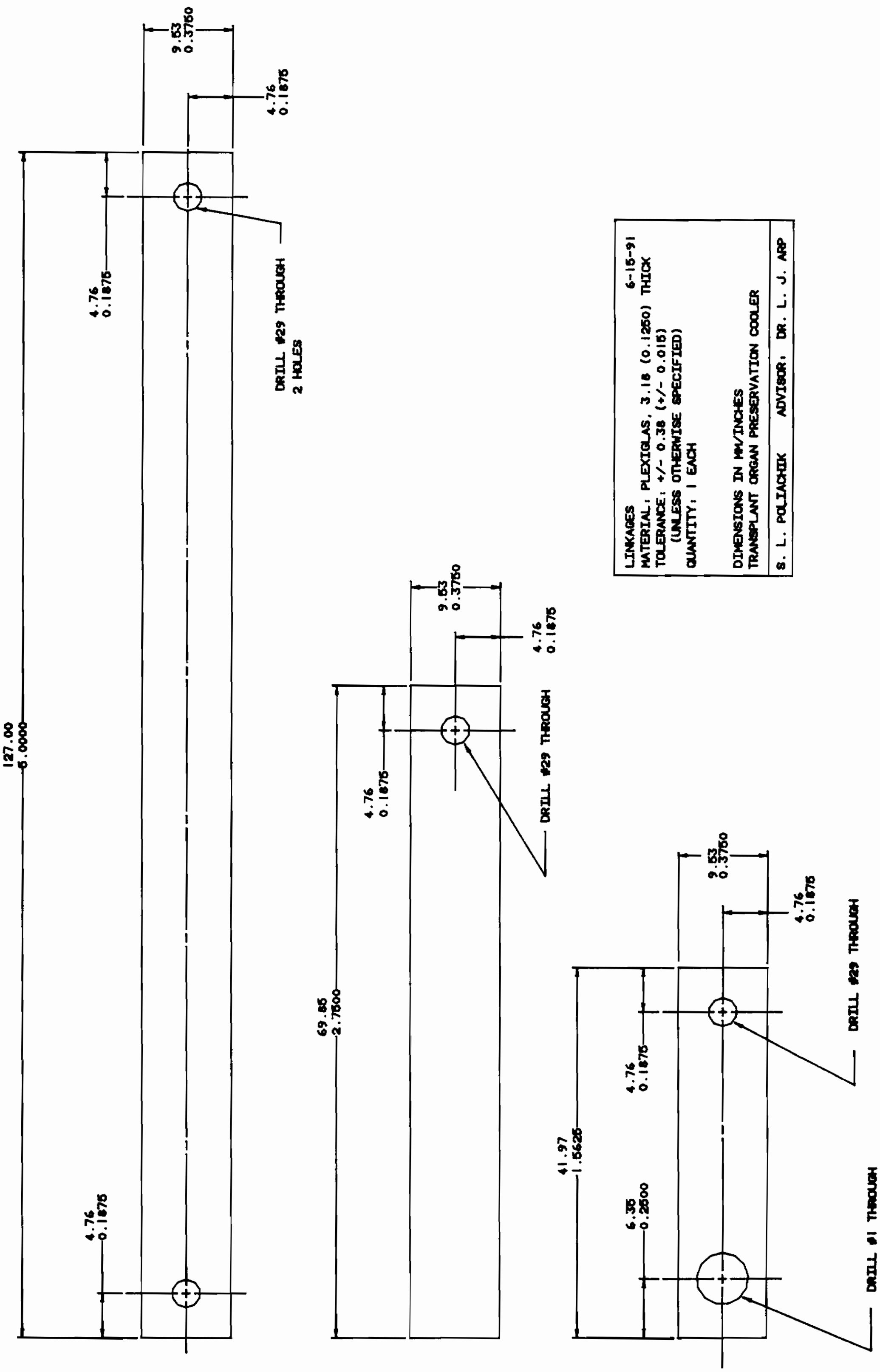


Figure 43. Temperature Control: Linkages to Bimetallic Coil

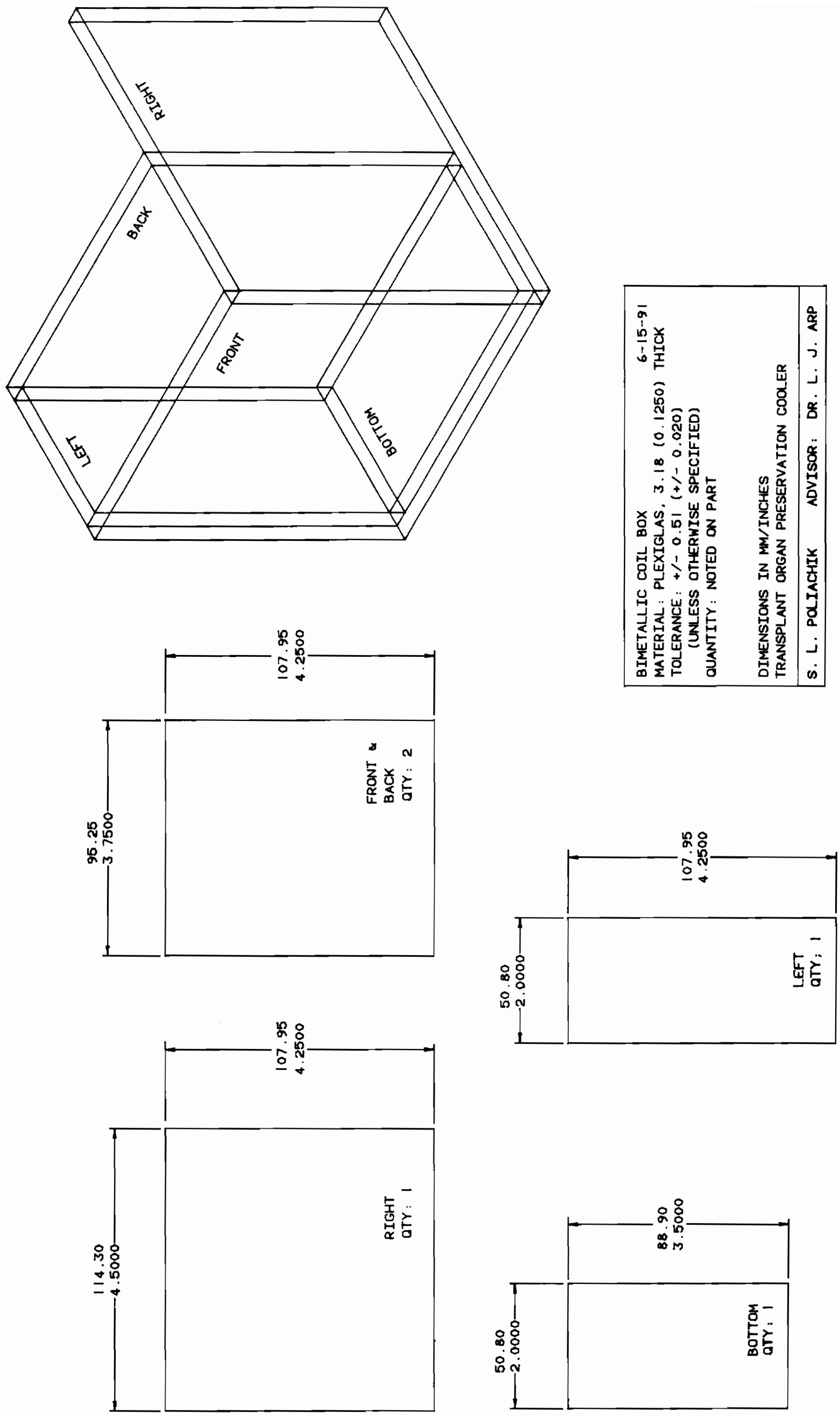


Figure 44. Temperature Control: Bimetallic Coil Box

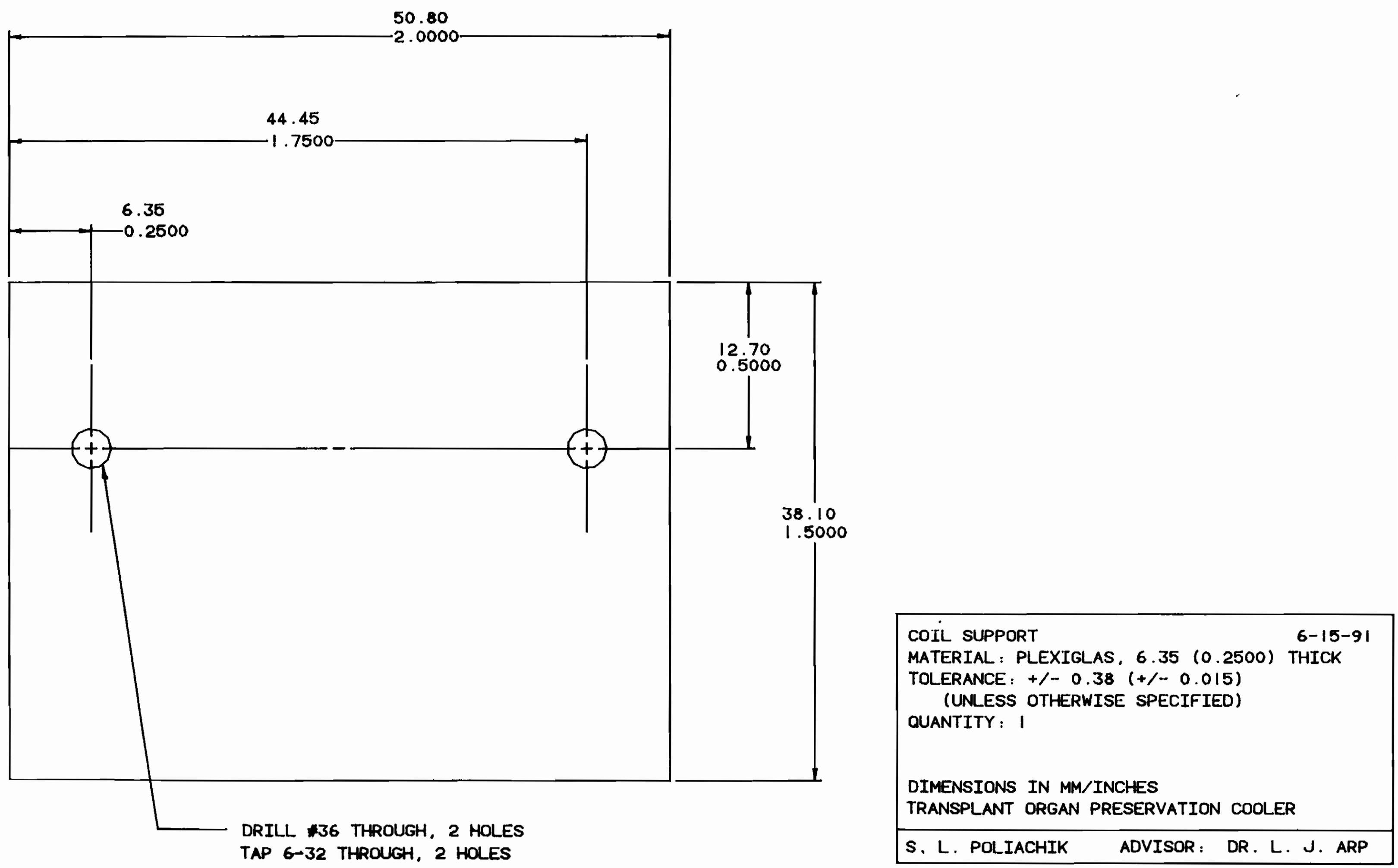


Figure 45. Temperature Control: Bimetallic Coil Support

Appendix C. Transplant Organ Preservation Cooler Test Results

Table 7. Test 1: Pump Rate of Pump Powered With Compressed Air; Room Temperature Ambient Conditions

Pump Rate (stroke/min)	Diaphragm Pump Rate (ml/min)	(in^3/min)
52	36.5	2.24
53	37.0	2.28
54	37.5	2.31
55	38.5	2.37
56	39.0	2.40

Result: 1 stroke pumps 0.7 ml (0.04 in^3/min)

Table 8. Test 2: Pump Rate of Pump Powered With Nitrogen; Room Temperature Ambient Conditions

Elapsed Time (hr)	**Pump Rate (stroke/min)**
0.0	46
2.0	45
3.0	38
3.5	42 (NV opened)
6.0	55 (NV opened)
6.5	50
8.5	-- (o-rings leaking)
9.5	-- (Dewars flask empty)

NV = needle valve

Table 9. Test 3: Cooler Temperature With Temperature Control Device Powered With Nitrogen; Room Temperature Ambient Conditions

Elapsed Time (hr)	Cooler Temperature (° C)	(° F)
0.00	2.0	36
0.17	2.5	37
0.33	2.5	37
0.50	2.5	37
0.67	2.5	37
0.83	2.5	37
1.00	3.0	37
1.17	3.0	37
1.42	3.0	37
1.75	3.0	37
2.00	3.5	38
2.17	3.5	38
2.42	3.5	38
2.75	3.5	38
2.92	3.5	38
3.17	4.0	39
3.42	4.0	39
3.75	4.0	39
3.92	4.0	39
4.17	4.5	40
4.42	4.5	40
4.75	5.0	41
4.92	5.0	41
5.17	5.0	41
5.42	5.0	41
7.42	6.0	43

Table 10. Test 4: Cooler Temperature, Ambient Temperature and Pump Rate of Preservation Cooler Powered With Nitrogen

Elapsed Time (hr)	Cooler Temp. (° C)	(° F)	Ambient Temp. (° C)	(° F)	Pump Rate (stroke/min)
0.00	3.0	37	33	91	77
0.25	3.0	37	36	97	75
0.50	3.0	37	37	99	86
0.75	3.0	37	38	100	86
1.00	3.0	37	38	100	84
1.25	3.5	38	38	100	78
1.50	3.5	38	38	100	84
1.75	3.5	38	38	100	84
2.00	3.5	38	38	100	87
2.25	3.5	38	38	100	86
2.50	3.5	38	37	99	114 (NV opened)
2.75	3.5	38	38	100	120
3.00	3.5	38	38	100	96
3.25	3.5	38	38	100	108
3.50	3.5	38	38	100	-- (fixing leak)
3.75	3.5	38	38	100	-- (fixing leak)
4.00	3.5	38	37	99	102
4.25	3.5	38	38	100	84
4.50	3.5	38	38	100	108
4.75	3.5	38	38	100	-- (fixing leak)
5.00	3.5	38	38	100	-- (fixing leak)
5.25	3.5	38	39	102	-- (fixing leak)
6.00	4.0	39	39	102	-- (fixing leak)
8.00	5.0	41	41	106	-- (fixing leak)
8.25	5.0	41	39	102	66

NV = needle valve

Table 11. Test 5: Cooler Temperature, Ambient Temperature and Pump Rate of Preservation Cooler Powered With Nitrogen

Elapsed Time (hr)	Cooler Temp. (° C)	(° F)	Ambient Temp. (° C)	(° F)	Pump Rate (stroke/min)	
0.00	3.0	37	36	97	32	
0.25	3.0	37	39	102	28	
0.50	3.0	37	40	104	39	(NV opened)
0.75	3.0	37	40	104	40	
1.00	3.5	38	40	104	40	
1.25	3.5	38	40	104	40	
1.50	3.5	38	40	104	40	
1.75	3.5	38	41	106	42	(NV opened)
2.00	3.5	38	41	106	44	
2.25	3.5	38	41	106	50	(NV opened)
2.50	4.0	39	41	106	53	
2.75	4.0	39	41	106	54	
3.00	4.0	39	41	106	53	
3.25	4.0	39	40	104	53	
3.50	4.0	39	41	106	54	
4.25	4.5	40	41	106	48	
4.50	4.5	40	41	106	57	(NV opened)
4.75	5.0	41	42	108	58	
5.25	5.0	41	41	106	50	(TP 18 psi)
5.50	5.5	42	40	104	66	(NV opened)

NV = needle valve
TP = tank pressure

Table 12. Test 6: Cooler Temperature, Ambient Temperature and Pump Rate of Preservation Cooler Powered With Nitrogen

Elapsed Time (hr)	Cooler Temp. (° C)	(° F)	Ambient Temp. (° C)	(° F)	Pump Rate (stroke/min)
0.00	2.0	36	34	93	47
0.25	2.0	36	38	100	49
0.50	2.0	36	38	100	52
0.75	2.0	36	39	102	52
1.00	2.0	36	40	104	50
1.25	2.0	36	41	106	51
1.50	2.5	37	40	104	-- (replace o-rings)
1.75	2.5	37	40	104	-- (replace o-rings)
2.00	2.5	37	39	102	51
2.25	2.5	37	40	104	52
2.50	2.5	37	40	104	51
2.75	2.5	37	40	104	51
3.00	2.5	37	40	104	52
3.25	3.0	37	40	104	49
3.75	3.0	37	40	104	55
4.00	3.0	37	41	106	55
4.25	3.0	37	41	106	55
4.50	3.0	37	41	106	55
4.75	3.0	37	41	106	54
5.00	3.0	37	41	106	53
5.25	3.0	37	41	106	53
5.50	3.0	37	42	108	54
5.75	3.0	37	42	108	53
6.00	3.0	37	42	108	54
6.25	3.0	37	42	108	50
6.50	3.5	38	41	106	50
6.75	3.5	38	41	106	53
7.00	3.5	38	41	106	53
7.25	3.5	38	41	106	50
7.50	3.5	38	41	106	51
8.00	3.5	38	41	106	48
8.25	4.0	39	41	106	50
8.50	4.0	39	41	106	52
8.75	4.0	39	41	106	53
9.00	4.0	39	41	106	52
9.25	4.0	39	42	108	54
9.50	4.5	40	40	104	52
9.75	4.5	40	40	104	-- (TP 20 psi)

TP = tank pressure

Vita

Sandra Louise Poliachik was born in Kingston, NY on January 24, 1964. She later moved to Damascus, MD, where she graduated from Damascus High School. Sandra graduated with a Bachelor of Science Degree in Mechanical Engineering from Virginia Polytechnic Institute and State University in June of 1987. She began her engineering career at Newport News Shipbuilding, where she worked until returning to Virginia Polytechnic Institute and State University in 1989. Sandra completed her Master of Science degree in Mechanical Engineering in August of 1991. She plans to work for Boeing in Everett, WA.

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