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# SURGICAL AND ENGINEERING RESEARCH ON MEANS OF FERTILITY CONTROL

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PROJECT I: NEW AND IMPROVED METHODS FOR POSTCONCEPTION FERTILITY CONTROL

Progress Report: August 1978

PROJECT I

AID/csd-3152

# NEW AND IMPROVED METHODS FOR POSTCONCEPTION FERTILITY CONTROL


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August 1978


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## SUMMARY

This paper reports progress and activities on Project AID/csd 3152 for the period January-June 1978. It is the last interim report on the project, which is in its closing phase. The project, directed toward the development of effective, durable, and economical instrumentation for vacuum termination of pregnancy, has achieved its primary objectives, as demonstrated by transfer of technology to various countries, international availability of instruments, and favorable clinical results as seen in studies of the IFRP and other clinical research organizations. Specifically, nonelectrical vacuum sources costing 1/10th to 1/20th of electrical equipment prices have been established and proven to give effective and safe service, covering clinical needs from MR procedures through second trimester D&E.

Most of the activity in the current 27-month contract phase has been directed toward refining designs and materials for the syringe aspirator and the hand-pumped aspirator. Both of these instruments have changed significantly in the contract period, achieving substantial economies through extended service life. The manageable gestation range for the hand-pumped aspirator has been extended by enlarging the collection container and through a modified design of the vacuum conservation valve. Tooling has been created for all of these innovations, and the latest generation instruments are now entering the field. The aspirator is being incorporated into the Bangladesh family planning program, along with syringes, through activities of private sector donors. The WHO is beginning a systematic, multinational study of the instrument.

The syringe aspirator has received particularly widespread acceptance in Asia, Latin America, and parts of Africa. It is estimated that between four and five million cases have accumulated since the original instrument was introduced in December 1973. The syringe is provided by U.S., Indian, Hong Kong, and Taiwanese suppliers, and the technology may readily be extended to additional countries.

Systematic studies of the hand-pump by the IFRP have shown a statistically significant and lower rate for delayed complications for the hand-pumped aspirator when compared to electrical aspirators. We thus appear to have

exceeded our goal of equal safety and efficacy, a result that is understandable in retrospect, and probably derived from the abrupt application of full vacuum with the hand-pumped system.

Ancillary research has served to identify more durable soft cannula materials which have been accepted by all major suppliers and led to extended service life. This has benefited cost and logistics for LDC projects, and probably improved safety by reducing problems associated with tips breaking off.

Limited studies of the effects of cannula pattern on tissue removal processes and uterine trauma have been persuasive with major suppliers and donors, resulting in appropriate redirection of emphasis on fielding less traumatic patterns in larger cannula sizes.

More exploratory research during the current contract period has been directed toward development of atraumatic tenaculae, and more importantly, safer and more effective techniques for cervical dilation. None of these developments has reached the point of transfer to commercial availability, although it is possible that the tenaculum will do so.

Through a technical directive and a subsequent revision to the workplan, we developed large aspiration cannulae, a rotary handle and enlarged collection tubing adaptations for the Berkeley aspirator These instruments were successfully used by Dr. Stubblefield for second trimester D&E, and results have been published. The instruments are being adopted by a commercial supplier.

In summation, the major objectives of establishing safe, economical and effective vacuum equipment for LDC use, independent of electricity, have been met. The results are beginning to be implemented internationally and the impact is already appreciable. Newer developments by Battelle just entering the field should broaden the impact even further and extend the remarkable economies already experienced with MR equipment to the full range of first trimester termination procedures.

## GENERAL BACKGROUND

In the early 1970s, accumulating clinical experience pointed to vacuum aspiration as a potentially useful technique for managing termination of

pregnancy, although the requirements for instrumentation were not at that time clear. The basic workplan for this project evolved in 1972, based in part on early work reported by Karman and Potts for very early interception and on the known characteristics of complex and expensive electrically pumped aspiration equipment.

The initial phases of the project were directed toward three objectives: 1) establishment of performance specifications for electrically driven aspirators (accomplished and used by AID Procurement), 2) development of an inexpensive, safe, and effective aspirator of small capacity (accomplished and first introduced on a broad scale in December 1973 at the Menstrual Regulation Conference), and 3) development of effective manually operated aspiration equipment for managing cases through the first trimester (accomplished late in 1973 in the form of an original design).

Subsequent activities have been directed toward transferring the technology of such systems to the commercial sector, both in this country and abroad, and collaborating with field users to refine the designs, materials, and instructional materials to optimize function, cost, and durability.

## CONTINUING RELEVANCE OF OBJECTIVES

The objectives of this work, as orignially defined, have actually become more relevant with time. The liberalization of abortion laws, which has occurred in parallel with the research, means that the outcome of the work is applicable to the majority of the world's women by law. The appropriateness of the technology which has resulted from Battelle's work has made it economically feasible to implement services. The low cost of the instruments has allowed a number of private sector organizations, among others, to continue provision of equipment and training to maintain the momentum of LDC service program development. This could not have occurred with the high-cost electrical aspiration equipment otherwise available.

Evolving data from the Center for Disease Control and other sources not only point up the clinical advantage of early vacuum interception over alternative traditional methods but also show a potentially important reduction in morbidity and mortality by applying D&E methods through about 16 weeks.

Although much attention has been directed toward pharmacologic approaches to pregnancy termination, nothing has surfaced which shows the safety, effectiveness, acceptability, and congruence with LDC conditions obtained with the equipment evolved by Battelle for vacuum aspiration.

The need for safer cervical dilation methods still persists. Although some promise has been shown by newer prostaglandin analogs, a clear solution to the problem is not yet apparent. Our own studies of the cervix have not yielded a clearly improved mechanical instrument for dilation. On the contrary, our findings so far indicate that we and the research community in general have had an inaccurate picture of processes governing cervical dilation. Although we do have some instruments which should provide an incremental improvement in safety, it is clear to us that work in new directions is emphatically needed to solve remaining problems.

## ACCOMPLISHMENTS

This section specifically adresses accomplishments within the current reporting period, separating these from the broader, preceding narrative and providing additional detail.

### VACUUM EQUIPMENT

Accomplishments in vacuum equipment fall into the following categories, discussed separately below:

- Final MR syringe design adopted by IPAS
- Enlarged valve version of syringe for later terminations
- Final hand-pumped aspirator design
- Receipt of clinical data on hand-pump performance
- Technology transfer activities for the hand pump
- Interactions with others on future hand-pump evaluations and field use
- Revised instructional materials for the hand-pump
- Recommendations on the Indian-made footpump
- Progress on a large cannula system for second trimester D&E
- Durable, rigid cannulae molding accomplished

## Final Syringe Design

The radical redesign of the syringe handle, totally replacing the original three-piece handle assembly with a single molded part and o-ring, has been validated as an improvement by laboratory tests and feedback from the field. This design has been reported and is shown in Figure 1. This revision, and minor changes to the valve liner, have been adopted by IPAS, and the final system is now being introduced in Bangladesh and a number of other countries. This new design should increase service life at least four-fold, thus substantially improving cost-effectiveness in mass programs.

## Enlarged Valve Syringe

Feedback from the field and observations in visited countries suggested that syringe use was limited primarily by the pinch valve's capacity to accept only small cannulae. Accordingly, we adapted a large pinch valve from the hand-pumped aspirator to the syringe, retaining the new handle as well. The resultant instrument, shown in Figure 2, directly accepts both Berkeley taper cannulae and Karman-type cannulae in sizes up to 12 mm (although we do not anticipate that sizes above 10 mm will be useful). The instrument can be readily recycled (or a second instrument picked up) to handle cases beyond eight weeks gestation. In skilled hands, it is probable that such an instrument can handle cases through twelve weeks gestation. The instrument was provided to consultants, including Drs. Potts and Branch, who represented two extremes of enthusiasm (or lack of it) for the instrument. Dr. Potts was most enthusiastic. Dr. Branch agreed that the instrument could handle later cases but found it messy and inconvenient to use. Some difficulties in cannula fitting were identified and corrected.

IPAS and their clinical advisors were most enthusiastic, and have acquired 40 units of the instrument from the molder for their own assessment. International reception has apparently been favorable, and it is likely that IPAS will make the instrument available.

Our own feelings are mixed. The hand-pumped aspirator doubtless does a better and more reliable job of managing later cases; and, when the cost is amortized over service life, the aspirator would actually be a better investment than the special version of the syringe. However, there are nontechnical restrictions which probably create a place for the new instrument in the international armamentarium. Older syringes already in the field can be retrofitted with the newer valve.

## Final Hand-Pumped Aspirator Design

During our foreign travel just prior to the current reporting period, we evaluated a simplified base assembly and a redesigned collection container in prototypical form through discussions with clinicians and observation of clinical procedures. With validation of the effectiveness and acceptability of these changes in hand, as well as feedback on the revised pinch valve design we carried in final molded form, we have been able to complete tooling for the new container assembly and to complete engineering drawings for the system. The most recent of changes has been addition of an O-ring to the valve end to assure secure cannula fitting. The system is shown in Figure 3. Engineering drawings are appended (Appendix A).

## Receipt of Data on Clinical Studies of the Hand-Pumped Aspirator

Data have just been received on IFRP studies initiated about 18 months ago, using the aspirator as it existed before improvements to the vacuum conservation valve and collection container. Results indicate that the complication rates for the hand-pumped aspirator are lower than for the electrical aspiration equipment used in controls. Data taken from the draft report are summarized in Table 1, which gives outcome for cases later than 14 days delayed menses, with most patients clustered round 10 weeks gestation. The immediate complication rates were 2.4% for the hand-pumped system, and 6.0% for the control group, a difference which was statistically significant ($p<.01$). The slight difference in followup complication rates, although in favor of the hand-pump, is not statistically significant.

These results, in addition to our own observations and discussions with consultants, verify that neither efficacy nor safety has been compromised in creating these inexpensive and durable vacuum instruments. Our original objectives thus appear to have been fully met.

## Technology Transfer Activities With the Hand-Pump

Because of the unsatisfactory performance of the Indian manufacturer identified earlier in the contract period, we terminated arrangements with him and forwarded technical information, drawings, and samples to a second Indian maker, whose past performance indicates higher interest and technical competence. These steps have just been taken, and it will not be possible to follow indigenous manufacure to completion within the brief time remaining under the contract.

TABLE I

MAJOR COMPLICATIONS

>14 DAYS DELAYED MENSES

| | Hand Pump Cases (N=500) | Electric Pump Controls (N=1876) | Total (N=2376) |
|---|---|---|---|
| IMMEDIATE COMPLICATIONS | | | |
| Uterine perforation | 1 | 5 | 6 |
| Suspected uterine perforation | 0 | 1 | 1 |
| Cervical laceration, sutured | 2 | 1 | 3 |
| Cervical laceration, not sutured | 0 | 19 | 19 |
| Blood loss over 100 ml. | 9 | 85 | 94 |
| Shock | 0 | 1 | 1 |
| Bleeding requiring curettage | 0 | 21 | 21 |
| Endometritis; parametritis | 0 | 1 | 1 |
| Salpingitis; adnexitis | 0 | 2 | 2 |
| WOMEN WITH ONE OR MORE MAJOR IMMEDIATE COMPLICATIONS | 12(2.4%) | 112(6.0%) | 124(5.2%) |
| FOLLOW-UP COMPLICATIONS | (N=458) | (N=1739) | (N=2197) |
| Bleeding requiring curettage | 9 | 29 | 38 |
| Salpingitis; adnexitis | 0 | 11 | 11 |
| Endometritis; parametritis | 0 | 1 | 1 |
| Other pelvic infection | 0 | 7 | 7 |
| Hemotometra | 0 | 5 | 5 |
| Pelvic hematoma, infected | 0 | 1 | 1 |
| FAILED PROCEDURES | | | |
| Retained products of conception | 0 | 4 | 4 |
| Continued pregnancy | 0 | 2 | 2 |
| WOMEN WITH ONE OR MORE MAJOR FOLLOW-UP COMPLICATIONS | 9(2.0%) | 59(3.4%) | 68(3.1%) |

Tooling for the latest revision to the hand-pump has been completed and is currently in place with a commercial molder. This accomplishment, in conjunction with the reduction in numbers of parts, machining operations, and other relatively expensive features of the earlier versions of the design, should lead to cost reductions. Close interactions have continued with IPAS, which has adopted the instrument and added it to their product line.

Within the last few weeks, a new organization, Vista Products, has surfaced, which has acquired tooling and inventories for some components from Burnett Instrument Company (makers of the original batch of instruments). It is not presently clear how this will affect availability of components to IPAS, the viability of continuing to supply IPAS with aspirators or the price to the LDC community. This new commercial activity is a surprise to us, and we are trying to determine how these developments will affect availability of the final aspirator design. The new organization has received an order for equipment to be fielded in Bangladesh, and will doubtless want to acquire parts from tooling now with our molder in Richland. The situation is complex, and we will keep you informed of developments as they occur.

Interactions With Others to Evaluate and Field the Hand-Pumped Aspirator

The World Health Organization will undertake a systematic, multinational study to compare the various vacuum sources, including the hand-pumped aspirator. We have informed Dr. Mark Belsey of the latest revisions to the instrument, and given our recommendation that this be the version subjected to their evaluation. Samples, photographs, and other technical details have been provided. As a result of discussions with Dr. Belsey and members of the WHO Task Force, we have received samples of cannulae they plan to use, along with some questions related to technical aspects of their planned research.

Similarly, we have kept the Pathfinder Fund informed on developments as they occur. As a result, both syringe and hand-pumped aspirators developed under AID research are being provided by Pathfinder for a privately-funded, large-scale training program in Bangladesh; this program is now in progress. Continuing assistance is provided in the form of technical information to this program.

Revised Instructional Materials for the Hand-Pumped Aspirator

Since the aspiration system has changed markedly during the current reporting period, we have completely revised the instructional materials, including both written matter and accompanying illustrations. Draft copies have been circulated to consultants and cooperating institutions for their comments, and we will prepare the final draft before the contract terminates.

A copy of the draft is appended (Appendix B).

Recommendations on Indian-Made Footpump

We have managed to informally work out a number of minor changes through correspondence with the maker of the Suctionaid-M footpump and with Chimco in Bombay, which is now distributing the unit through India. We have backed away from the idea of radical changes to the apparatus for a number of reasons (including an unenthusiastic response from our consultants and minimal interest from the IFRP). Accordingly, we have recommended three minimal changes needed to make the instrument useful and acceptable. These are:

1) Modification of the collection container to provide a minimal clear aperture of 10 mm
2) Provision of more flexible collection tubing
3) Addition of a vacuum conservation valve, preferably following the latest Battelle design (two plunger, Berkeley taper configuration).

These suggestions have been accepted, and the system is being modified accordingly.

Progress on Large Cannulae System for Second Trimester D&E

Studies using the prototypical 16-mm cannula, rotary handle and enlarged collection tubing have been completed and published (Fertility and Sterility, 29:5, May 1978). Tooling for the rotary handle and molded parts have been completed, with work performed in Richland. Blow molding tooling for 16-mm cannulae and molded cannulae have been obtained from Rocket of London. A more flexible, corrugated collection tubing has been located and procured. Samples of these molded and commercially available parts have been supplied to Dr. Stubblefield at Harvard and have received a favorable evaluation. Rocket of London has already added the cannula to their catalog, and it is now commercially available.

Experiments by Rocket to blow mold large cannulae from TPX have been unsuccessful. Although extruded tubing looked satisfactory, apparently their control of temperature uniformity during the molding step is inadequate. Since the IFRP has backed away to a preliminary, small-scale evaluation of D&E using this instrumentation, we have accepted large cannulae from PVC rather than expend more time seeking TPX cannulae.

Supplies to support IFRP studies will be sent within the contract period, as they are now in hand.

Durable Rigid Berkeley-Type Cannulae

Through a long and informal process of persuasion, we have managed to convince Berkely Bio-Engineering to try molding cannulae from TPX. They have just managed to do so, and are currently considering whether they will make these available to LDC users. My instinct is that this decision will be favorable.

## ANCILLARY INSTRUMENTS AND SPECIAL TECHNICAL ACTIVITIES

In addition to final development of the basic vacuum equipment and cannulae, progress has also been made on three other research tasks:

- cervical dilators
- tenaculae
- transfer of elastic band technology

### Cervical Dilation

Measurements of tissue properties as a function of anatomic location have been completed with the assistance of our consultant, Dr. John T. Conrad. Results have been written up in a paper to be presented at the International Conference on the Human Cervix to be held in Montreal in August 1978. A copy has been submitted to AID for approval.

In essence, work by Conrad has shown that the major resistance to dilation lies in a 5-mm thick annulus of tissue immediately adjacent to the cervical endothelium at the level of the inner os. These modulus measurements as a function of distance from the cervical canal are useful in understanding the location of resistance to dilation and in translating grossly measured applied loads into an appreciation of load per unit area. In addition to variations in radial properties, differences in stiffness between regions

at the isthmus, inner os and outer os have been quantified. These follow clinical impressions quite closely, and add very little that is new.

Observations of cervical dilation with the bivalve dilator, particularly with excised tissues which may be sectioned subsequent to dilation, have clarified the mode of action more than force quantitation has done. The model of tensile stress acting to distend the tissue (much as the rubber band), which we and others have consistently applied, appears to be wrong. The area of tissue under compression from the dilator blades moves away, and the area presumed to be in tension does not stretch, but rather flows in between the opening blades. The peripheral structure of the organ appears to be unchanged, and does not appear to be under any great load. Although it is a great simplification, a better model of the cervix would be to regard it as a spongey cylinder restrained at its outer boundaries. A further extension of this model would explain the tissue behavior in part by hydrostatic principles, wherein much of the dimensional change is accounted for by movement of water. In the short-term loading experiments, such water would logically be interstitial rather than intracellular.

The originally hypothesized model for the behavior of the cervix with the bivalve dilator is shown in Figure 4a. Figure 4b shows the actual configuration of the cervical tissue and dilator blades as observed in our in-vitro experiments. This experience, along with the strain-rate dependence of modulus, tends to support a new hypothesis of cervical dilation. This approach, although it does not discount the role of collagen binding and progressive loading of collagen fibers, adds the consideration of water mobility as a major component of cervical tissue behavior.

This hypothesis explains much experimental and clinical experience on tissue distension and agrees with the wisdom of slow, gentle dilation based on the probable rate limitation of conceiveable water mobility mechanisms at the microstructural level. Perhaps most importantly, recognition of the probable role of water mobility opens a whole new area for applied research directed toward improving the mobility of water within the tissues, using relatively cheap and innocuous substances to modify conductivity across cellular membranes and water bonding.

An experiment has been designed to look at the possibility of water mobility as a possible explanation of dilation. Although it is not entirely conclusive

and only two cervices have been tried, the results tend to support the idea of a significant role for movement of interstitial water. In this experiment, using freshly excised, nonpregnant organs, we first pass a small dilator with minimal force through the os, and leave it in situ. Moderate compressive force is then applied to a hoop placed around the perimeter of the organ in the region of the inner os. Force is removed, the dilator withdrawn, and the next size of dilator passed without resistance. The process of gently squeezing the cervix against in situ dilators is carried out throughout the range of dilators available--so far limited to 12 mm. The finding thus far is that the cervix can be dilated to 12 mm without the application of any significant force to insert progressively larger dilators. However, we noted some increase of force in the second of two specimens in dilation above 9 mm. This appeared to be associated with an unusually small corpus uteri, and may be due to a narrow lumen in the lower uterine segment. Some interference with an in situ IUD was also noted in attempts to pass larger dilators.

We regard this insight as a fundamental and highly valuable one. However, it does appear to invalidate much of our original thinking and that of virtually all other investigators on dilation processes and instruments. Although the mechanical approaches we have investigated probably do provide some incremental improvements in safety, they do not appear to be revolutionary. Briefly, we have three dilator approaches which have seen some limited clinical use:

1) The bivalve dilator, which has been made up in a spring-loaded version acting as a mechanical laminaria, functions and could be designed to apply dilation forces at safe levels, taking the matter of strain rate out of the hands of the clinician. We have lost much time with this instrument in interactions with John Hopkins investigators and do not expect to fully develop this instrument in the time remaining.
2) An inside-out dilator, basically consisting of a collapsed balloon passed into the uterine lumen and expanded to a rigid form above the level of the isthmus. This is then pulled outward through the isthmus and inner os under tension, applying counter pressure (rather than traction) on the cervix. Initial clinical impressions from Dr. Solderstrom are not good, and for unexplained reasons extraction forces appear to be unreasonably high.

3) A dilation approach similar to 2, but simpler in embodiment, is the use of multiple small rods with enlarged distal ends. So far, these have been clinically used in groups of three, yielding dilations in the range of 6 to 8 mm. This arrangement is shown in Figure 5. The clinical impression is favorable, although not enthusiastic. This type of dilator not only eliminates significant countertraction on the lip of the cervix, but also eliminates the need for forceful, upward passage of the cervical canal with the dilator; this in turn should eliminate perforations, lateral tears into the uterine arteries, and cervical lacerations requiring sutures.

We plan to obtain additional clinical impressions of this new approach and to prepare a brief description for the open literature (perhaps in Contraception).

Tenaculae

With the assistance of Dr. Brenner, we have gone through several modifications to the jaw's shape based on his observations, measurements, and comments. We have forwarded what we hope to be final versions of this instrument to him for appraisal. Final action will be to publish a short note on the device and share details with commercial firms having an interest in the instrument.

Elastic Band Technology Transfer

Initially under a technical directive and subsequently under a new task in the approved workplan, we supplied technical information and materials to Chimco Bio-Engineering in Bombay, India for indigneous manufacture of elastic bands for female sterilization. Evaluations of materials and of Indian-made products through laboratory tests have supported the development of band cutting, packaging, and sterilization processes in India. The Indian product is now on the market and is available for distribution throughout the subcontinent through Chimco.

We have supplied additional elastomeric materials and technical information on heat treating of drawn stainless steel tubing to Chimco during the reporting period. The packaged Indian product is shown in Figure 6.

## DISSEMINATION AND UTILIZATION OF RESEARCH RESULTS

The most direct dissemination of research results continues to be placement of newly developed instruments into the commercial sector by making results available to known manufacturers in a nondiscriminatory way. Battelle developments are also provided to various research organizations and donor groups for their evaluation.

In this way, equipment has been provided for comprehensive international studies of MR by the International Fertility Research Program. Clinical statistics substantiating the efficacy and safety of MR and early abortion techniques have been extensively published by the IFRP and their contributors. Early in the program (1973) an international conference on Menstrual Regulation was held, marking the beginning of these international studies. The outcome, 5 years later, has been fielding of approximately 100,000 syringe aspirators in Asia, Latin America, and Africa, and performance of an estimated 4 to 5 million cases.

Basic developments on vacuum aspiration equipment have been reported in the open literature, notably in the 1975 issue of Advances in Planned Parenthood and in the proceedings of the Pathfinder-sponsored Airlie Conference of Latin Americans held in 1976. By now, most dissemination of information through the open literature has passed outside of our hands and is being generated chiefly by clinicians and clinically-oriented institutional programs.

Products developed under this contract are being fielded by International Planned Parenthood Federation and by the Pathfinder Fund. Through correspondence, we continue to share technical information supportive of multinational studies of the hand-pumped aspirator now beginning under the auspices of the World Health Organization. Such correspondence, in conjunction with the Advances in Planned Parenthood paper from 1975, supply key background information for the WHO Task Force and contributing centers. Information on the final aspirator design and on sources for it have been supplied to the Pathfinder Fund, and such information is of key importance to a new training project for MR and first trimester MTP beginning in Bangladesh this summer.

Provision of technical data to LDC technologists has led to availability of indigneously-made MR syringes and sterilization bands, and is expected to lead to availability of indigenously-made, manually operated vacuum systems as well.

A draft paper has just been received describing the findings of IFRP trials of the hand-pumped aspirator in India, and this will be integrated with our own experiences in modifying the instrument to create a single publication.

Papers remain to be prepared describing findings on tissue-level studies of differing cannulae, on revised tenaculum design, and on newer approaches to cervical dilation.

## FUTURE PLANS

Developmental and laboratory efforts are now complete. In the closing weeks of this project, we will expend most of our effort on consolidating information for final reporting and on communicating technical details to commercial suppliers and to other organizations engaged in international trials or distribution of instruments.

We will suggest specific problems requiring additional effort, either by Battelle investigators or others in the research community in the Final Report.

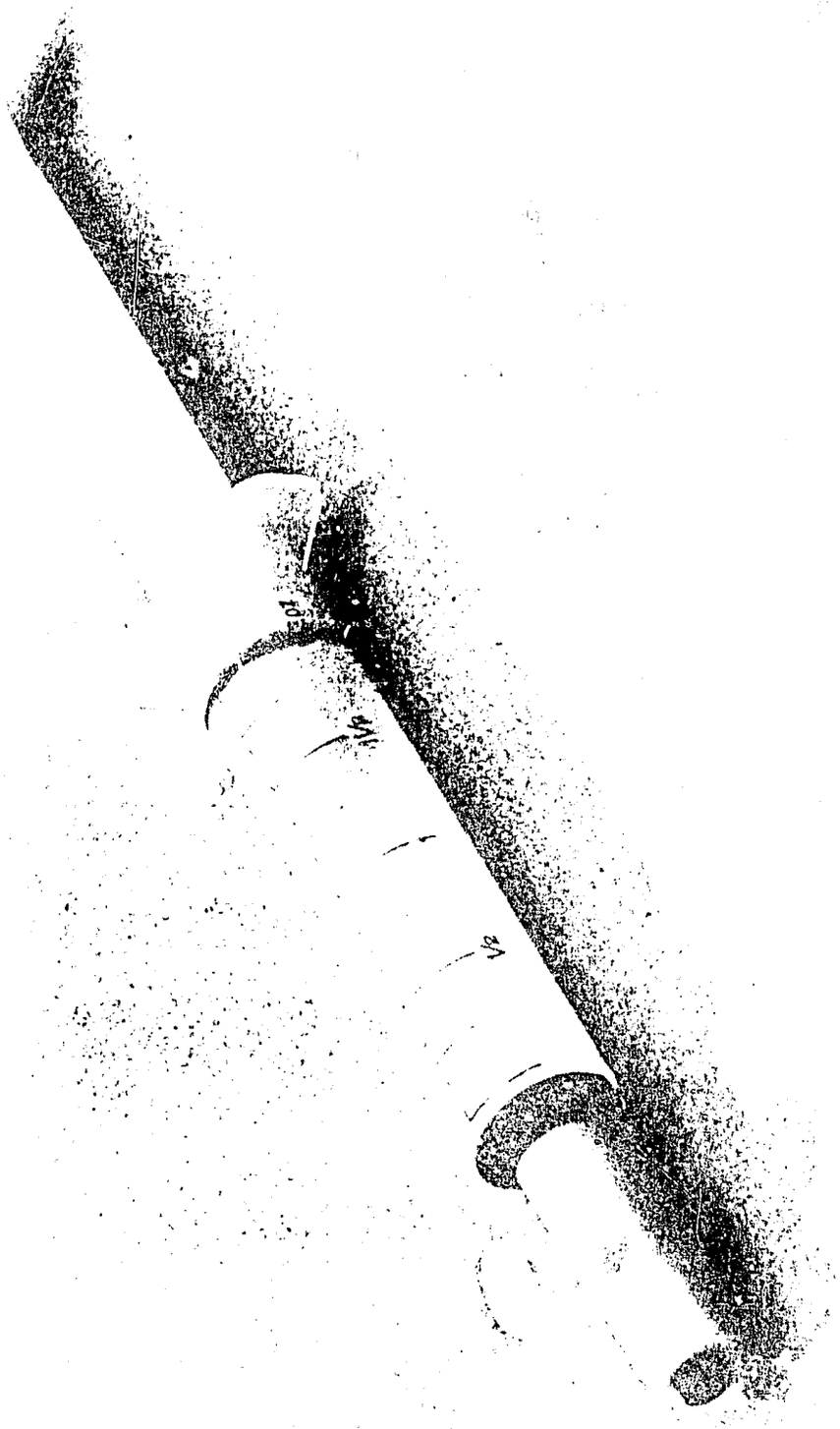


Figure 1. Final MR Syringe Design, with D-ring Handle

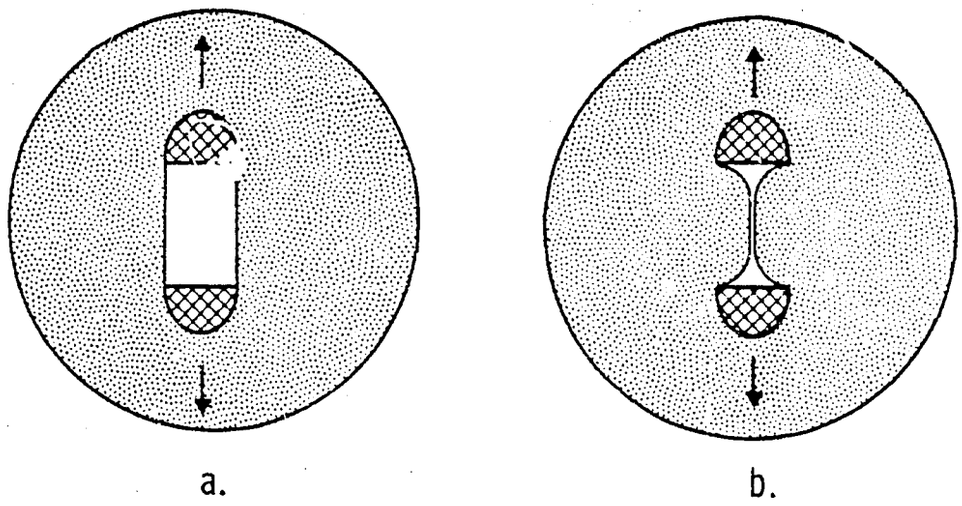



Figure 4. Cross Sectional View Showing Action of Bivalve Dilator; a. as hypothesized. b. as observed.

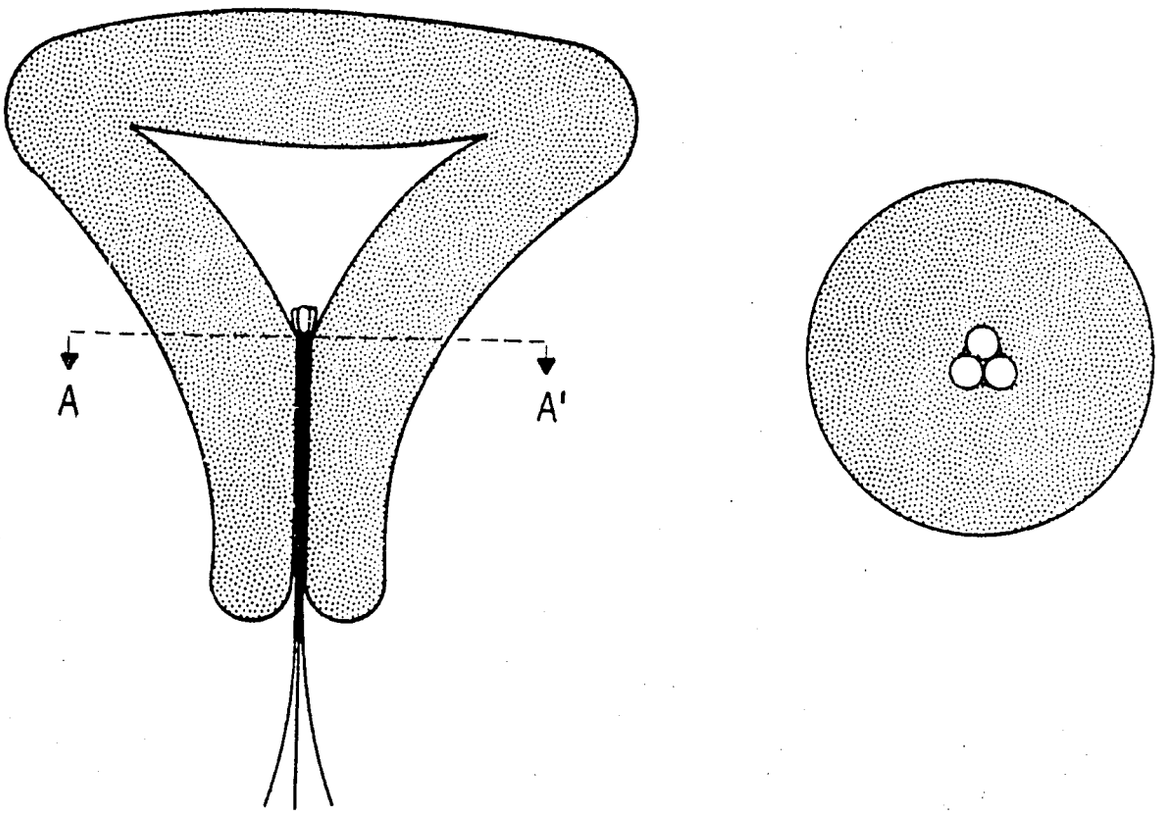



Figure 5. Multiple Devices Used for Inside-out Dilation

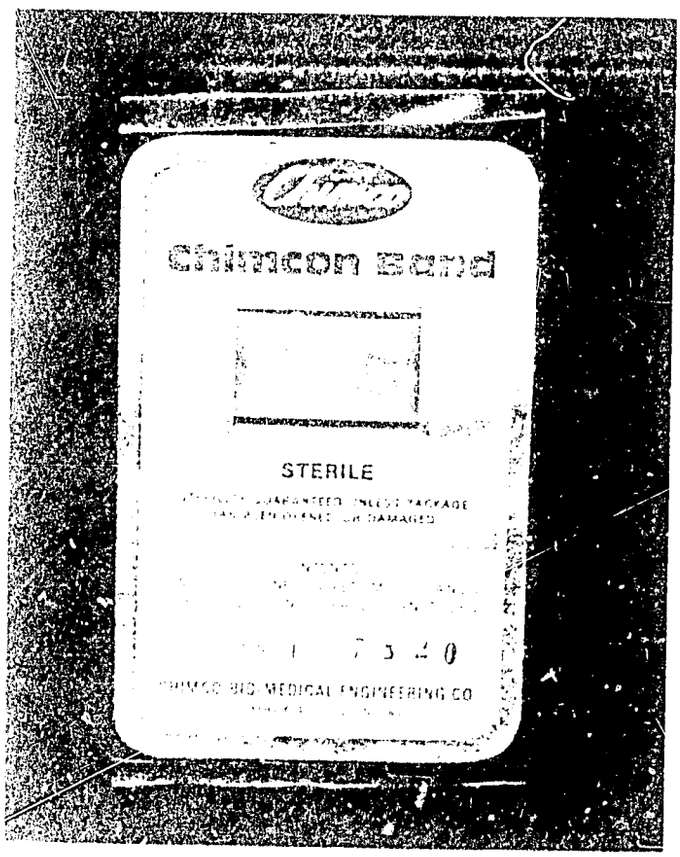



Figure 4. Silicon-made Band for Female Sterilization

APPENDIX A

# USER'S MANUAL FOR THE HAND-PUMPED UTERINE ASPIRATOR

## I. GENERAL DESCRIPTION

The IPAS hand-pumped uterine aspirator has been especially developed for gynecologic procedures such as menstrual regulation, elective first trimester pregnancy termination, treatment of septic or incomplete abortion and therapeutic D&C. The basic design was established in 1973, and has subsequently been proven and refined through clinical use in a number of countries.

The vacuum system consists of a manually operated vacuum pump and collection container mounted together on a single base. The base has a large suction cup for holding the system firmly to any smooth surface. The system includes a simple pinch valve which conserves vacuum and which fits directly onto aspiration cannulae. The assembled system is shown in Figure 1.

The system will handle approximately 700 cc of aspirated volume, and can be used with cannulae up to 12 mm diameter. A maximum vacuum level of 70 cm Hg can be obtained, making the apparatus equal to the best electrically driven aspirators.

This manual contains instructions for proper assembly, use, maintenance and repair of the aspirator. Please read it carefully.

## II. COMPONENTS

The aspirator is supplied in a carrying and storage case. It consists of the following components:

1. A base with an attached large suction cup and two, specially molded parts for attaching the pump and collection bottle
2. A hand-operated vacuum pump
3. A collection bottle and lid
4. A double-plunger pinch valve to control vacuum
5. A length of smaller diameter tubing to join the pump and collection bottle

6. A length of larger diameter collection tubing

7. A simple, collapsing tube vacuum indicator

These parts are identified, by number, in Figure 1. In addition, a dial vacuum gauge, not shown in the figure, is supplied for calibration and testing of the system.

## III. ASSEMBLY

The IPAS aspirator can be assembled and disassembled without tools. The following assembly order is a convenient one:

- Pull out the lower end of the pump a few inches, lifting the locking ring (a) away from the locking rubber stopper (b), as shown in Figure 2. Seat the stopper fully in the pump base (c), and then press the locking ring (a) down over the stopper. This locks the pump onto the base.
- Attach the smaller diameter flexible tubing to the smaller tapered fitting on the container lid.
- Attach the larger diameter flexible tubing to the larger diameter tapered fitting on the container lid.
- Press the tapered end of the pinch valve into the free end of the large diameter tubing.
- Place the collection container on the base.
- Put the lid on the container.
- Connect the free end of the smaller diameter tubing to one of the tapered fittings on the pump base.
- Connect the collapsing tube vacuum indicator (the short length of surgical tubing with one end sealed by a plastic ball) to the other tapered fitting on the pump base, pushing it fully over the fitting.

The system is now assembled and should produce and hold a vacuum. This can be tested by closing the pinch valve and pumping the system down. To close the valve, press both buttons fully down and tilt them forward to

lock them in the closed position. The valve is shown fully open in Figure 3a and fully closed in Figure 3b.

With the valve closed, operate the pump through about 12 full strokes. The collapsing tube vacuum indicator should collapse as shown in Figure 3b, showing that a vacuum of about 51 cm (20 in.) Hg has been reached. If all connections are properly tight, the system should hold this vacuum for several hours.

NOTE: IT IS IMPORTANT THAT FULL STROKES BE TAKEN WITH THE PUMP FOR EFFICIENT OPERATION, AS ILLUSTRATED IN FIGURE 4.

## IV. CALIBRATION OF THE COLLAPSING TUBE VACUUM INDICATOR

Conventional dial-type vacuum gauges are delicate instruments, easily knocked out of adjustment by mechanical shock and subject to damage by ingestion of fluids. Accordingly, a simple, indestructible vacuum indicator has been provided with this aspirator and is recommended for routine clinical use of the system.

The indicator is based on the simple principle of using atmospheric pressure to collapse an evacuated rubber tube. The rubber tube is closed at one end by a plastic ball and is connected to the pump base as noted in the preceding assembly sequence. It is thus connected to the evacuated system, and the pressure within the rubber tube is the same as that within the collection bottle.

The rubber tube is unsupported along the portion of its length which lies between the plastic ball in one end and the tapered fitting on the pump base. The amount of vacuum required to collapse the rubber tube is very much a function of the unsupported length of the tube; that is, the longer the unsupported length of tube, the easier it is to collapse. Once the unsupported length is reduced beyond a certain point, it does not collapse even under very high vacuum.

The user can calibrate the collapsing tube vacuum indicator by adjusting the unsupported length of the tube and observing the collapse point in comparison to the dial vacuum gauge supplied with the system. One way to

do this is shown in Figure 5. In this figure, the smaller tube connecting the pump base to the collection container has been disconnected, and the dial gauge has been connected in its place. Figure 5a shows the rubber indicator when there is no vacuum in the system. Figure 5b shows the rubber indicator fully collapsed at a vacuum of 70 cm (28 in.) Hg.

Alternatively, the system can be operated as assembled, pushing the dial vacuum gauge into the distal end of the pinch valve to monitor the vacuum level. (In this case of course the valve is left open to connect the gauge with vacuum in the system).

Whichever method is chosen, the most effective setting appears to be about 51 cm (20 in.) Hg; that is, the rubber tube should begin to recover from its collapse at about 51 cm (20 in.) Hg vacuum. Less vacuum than this appears relatively ineffective for uterine aspiration.

Once the collapsing tube indicator has been calibrated, the dial gauge can be placed in safe storage for future checks and recalibration of the system.

## V. USE

The aspirator is most conveniently used on the floor or on a low table to one side of the operator. The suction cup base is designed to adhere to a smooth surface, allowing one-handed operation. Lacking a smooth surface, the base can be held down with the foot or hand during pumpdown.

The system can (and should) be pumped down in advance of need. Since the aspirator is leak-resistant, it will hold vacuum until it is needed. Pumping down before beginning the procedure assures that the unit is functioning properly and is also less disturbing to the patient.

The system is evacuated by closing the pinch valve and locking it, as shown in Figure 3b. The pump is then operated in fully extended strokes as shown in Figure 4. Full strokes are important because the pump pulls air from the collection bottle on the downward stroke and expels it from the pump on the upward stroke. If the pump is not fully lifted, then air remains in the pump and operation is very inefficient.

The attained vacuum as a function of the number of pump cycles is given in Table 1 for a typical aspirator. Thus, in clinical use, the amount of vacuum can be controlled by the number of strokes taken to prepare the system for use. The attainment of vacuum can be verified by observing the collapsed rubber tube vacuum indicator, as previously shown in Figure 3. Unless vacuum is lost by inadvertently withdrawing the cannula opening from the cervix, the vacuum from the first pumpdown of the system should be more than adequate for completion of any first trimester procedure, with blood and tissue volumes of up to 700 cc.

TABLE 1. Attained Vacuum as a Function of Pump Cycles

| Number of Cycles (1 cycle = 1 upward and 1 downward stroke) | Vacuum Cm Hg (in. Hg) |
|---|---|
| 3 | 26 (10) |
| 6 | 38 (15) |
| 10 | 51 (20) |
| 20 | 64 (25) |

## Attachment of Cannulae

The pinch valve is designed to accept a standard taper, and the kit includes rigid cannulae (8 to 12 mm diameter) which directly fit the valve without use of adapters. It is important that the tapered cannula end be fully and securely pushed into the distal end of the pinch valve so that air leakage is avoided.

Soft cannulae of the Karman pattern can be used with the system by means of special adapters supplied in the kit. These adapters fit cannulae of 5 and 6 mm diameter and have the same taper as the rigid cannulae. Again, it is important to push adapters fully and securely into the distal end of the pinch valve to avoid air leakage.

## Conservation of Vacuum

The effectiveness and convenience of a manually operated vacuum aspirator depends on the ability to hold vacuum and to control it. The pinch valve is an essential feature of the aspirator, and its proper use can minimize effort needed to maintain vacuum.

The pinch valve is closed to establish vacuum and remains closed until the cannula has been passed into the uterine lumen. The valve is then opened by squeezing down on both buttons and rocking these backward to unlock them. Both plungers of the valve will then fully lift, opening a pathway between the cannula and the collection tubing, and initiating the aspiration of uterine contents.

The human cervix serves as a very effective vacuum seal, and there will be no loss of vacuum in the aspirator unless the cannula aperture is withdrawn below the cervix. It is sometimes necessary to withdraw the cannula to clear the aperture or to check completeness of uterine evacuation with a curette. In these instances, vacuum in the aspirator can be conserved by closing the pinch valve and locking it before withdrawing the cannula. Through use of the pinch valve, the operator can almost always complete a procedure without any need for additional pumping.

Another important function of the pinch valve is to immediately stop aspiration in the event of perforation, simply by closing and locking the valve.

## VI. ROUTINE CARE

Once the clinical procedure has been completed, cleaning is facilitated by aspirating clean water through the cannula, valve and collection tubing. The pinch valve can be used to limit the rate of water aspiration and avoid splashing of fluids in the collection container.

### Cleaning and Lubricating the Pump

Unless blood is ingested by the pump, the only part of the system requiring routine washing should be the collection container, collection tubing and pinch valve.

All parts of the aspiration system can be cleaned with soap and water or mild detergent. Abrasive cleansers should be avoided since the plastic components are easily scratched. Plastics are also damaged by some chlorinated hydrocarbons, esters, aromatics and aldehydes, and these should be avoided.

To clean and lubricate the pump is a simple task, and no tools are needed. Refer to Figure 6 for identification of internal parts. Remove the pump assembly from the base. To disassemble the pump, grasp the outer

pump tube and pull the inner pump tube (1) out slightly. Then knock off the lower pump end cap (2) at the bottom end of the pump assembly as in Figure 7. The edge of a table or the base assembly works nicely. Slide the outer pump tube off the inner pump tube assembly. The inner pump tube (1), front pump seal (3), pump connector stopper (4), stopper locking ring (5), and piston (6) are now exposed for cleaning and lubrication.

The piston (6) is equipped with an O-ring (7) which can be removed, if necessary, to wash the pump. Just below the piston is a thin rubber band that acts as a check valve (8). The check valve (8) must be positioned so that it lies flat and covers all the round holes in the shallow groove on the inner pump tube. The O-ring and check valve can be taken off without any tools, but the wooden handle of a cotton swab is sometimes helpful in prying up the O-ring. Sharp tools which might cut the rubber or plastic should not be used.

Unless the pump has ingested blood, the old lubricant can simply be wiped off. If washing is necessary, mild detergent or soap should be used. After washing in sudsy water and rinsing, the pump should be dried thoroughly, lubricated properly, and reassembled for use. The pump must be lubricated with silicone grease.

To lubricate and reassemble the pump, follow the sequence below. Refer to Figure 6 for component identification.

1. Put a small amount of silicone grease (about 0.5 cc) on the O-ring seal (7) and smear it completely around the ring and groove. The rubber band check valve (8) should be given a light film of silicone grease.

2. Smear some silicone grease on the upper part of the inner pump tube shaft (1) which slides against the front pump seal (3) and insert the piston end of the assembly into the outer pump tube. Some force is required to compress the O-ring seal.

3. Smear some silicone grease on the inside of the front pump seal (3) and push it (flat side first) over the inner pump tube so that it seats in the beveled (bottom) end of the outer pump tube.

4. Slip the lower end cap (2) onto the outer pump tube and knock it firmly into place. This can be done by striking a table edge or by using the edge of the base assembly to hammer with (Figure 7).

5. Stroke the pump fully many times until the grease is evenly spread. If there is too much grease, you may need to wipe some of it off. Knock the pump apart and wipe excess grease from the check valve area, if necessary.

6. Install the compression ring (5) and pump connector seal (4) as shown in Figure 6.

7. Connect the pump to the base and check to see that everything works properly.

Storage

To prolong life of the O-ring in the container lid, the container should be stored with the lid removed or only loosely in place. To prolong life of the pinch valve, it should be stored open. The tight fit of flexible tubing connections can be extended by disconnecting these when the system is not in use.

## VII. PERIODIC MAINTENANCE AND REPAIR

Unless the pump ingests blood or fluid, the system should require little attention and should provide years of service before any major part needs replacement. The pump should be lubricated two to three times per year, depending on the degree of use.

Generally speaking, if the system is checked periodically and found to be functioning properly, no action is indicated. Such checking occurs to some extent during routine use (i.e., does the system pump down readily in advance of each procedure, and does it hold vacuum until needed?). However, it is prudent to perform some simple tests at the beginning of each day to assure that the system is operating properly.

Tests

1. Securely fit the dial vacuum gauge into the distal end of the pinch valve (Figure 8). With the valve open, take 20 full strokes of the pump. Approximately 64 cm (25 in.) Hg vacuum should be indicated.

2. With the pinch valve closed and the dial gauge removed, allow the system to sit for 15 minutes. The rubber tube vacuum indicator should remain collapsed. On reconnecting the dial gauge and opening the pinch valve, the vacuum level should be essentially unchanged following the 15 minute test.

If these two conditions are met, the system is working properly and does not require attention.

Problems and Probable Causes

The major problems, probable causes and corrective actions likely to be encountered with the aspirator system are listed in Table 2.

TABLE 2. Causes and Solutions to Problems with Aspirator System

| Problem | Probable Cause | Required Action |
|---|---|---|
| System functions and attains vacuum, but requires too many strokes. Holds vacuum when reached. | Lack of sufficient lubrication | Lubricate pump |
| | Pump O-ring worn | Replace pump O-ring |
| System takes too long to reach vacuum; then vacuum is lost rapidly | Leaks in tubing, pump stopper or O-ring seal of collection container | Check all connectors, tighten if necessary. Replace damaged stopper, tubing or O-ring |
| | Broken pinch valve liner | Verify by removing valve and replacing with another or by plugging collection tube. If valve is faulty, replace. |
| Pump does not function. Vacuum is produced on downstroke and lost on upstroke. | Faulty check valve band | Replace check valve band |

## VIII. CHECK VALVE REPAIR

Replacement check valve bands are provided for pump repair. However, should these be lost or used up, emergency check valve bands can be cut from the thumb of a large (No. 9) surgical glove with scissors. Holding the glove thumb flat between sheets of paper makes it easier to get a straight cut. Cut the bands about 27/64 inches (11 mm) wide. The easiest way to put on a new band is to stretch it across fingertips and thumb, reach over the piston cap with the

band expanded, and lay it carefully in the groove so that it lies flat. With the new check valve in place, reassemble the system and test it by connecting the dial vacuum gauge to one side of the pump base. The repaired pump should reach an ultimate vacuum of at least 64 cm (25 in.) of mercury. If it will not pump down that far the check band is too tight, and should be replaced with one of a slightly larger diameter.

4
3
6
7
11
1

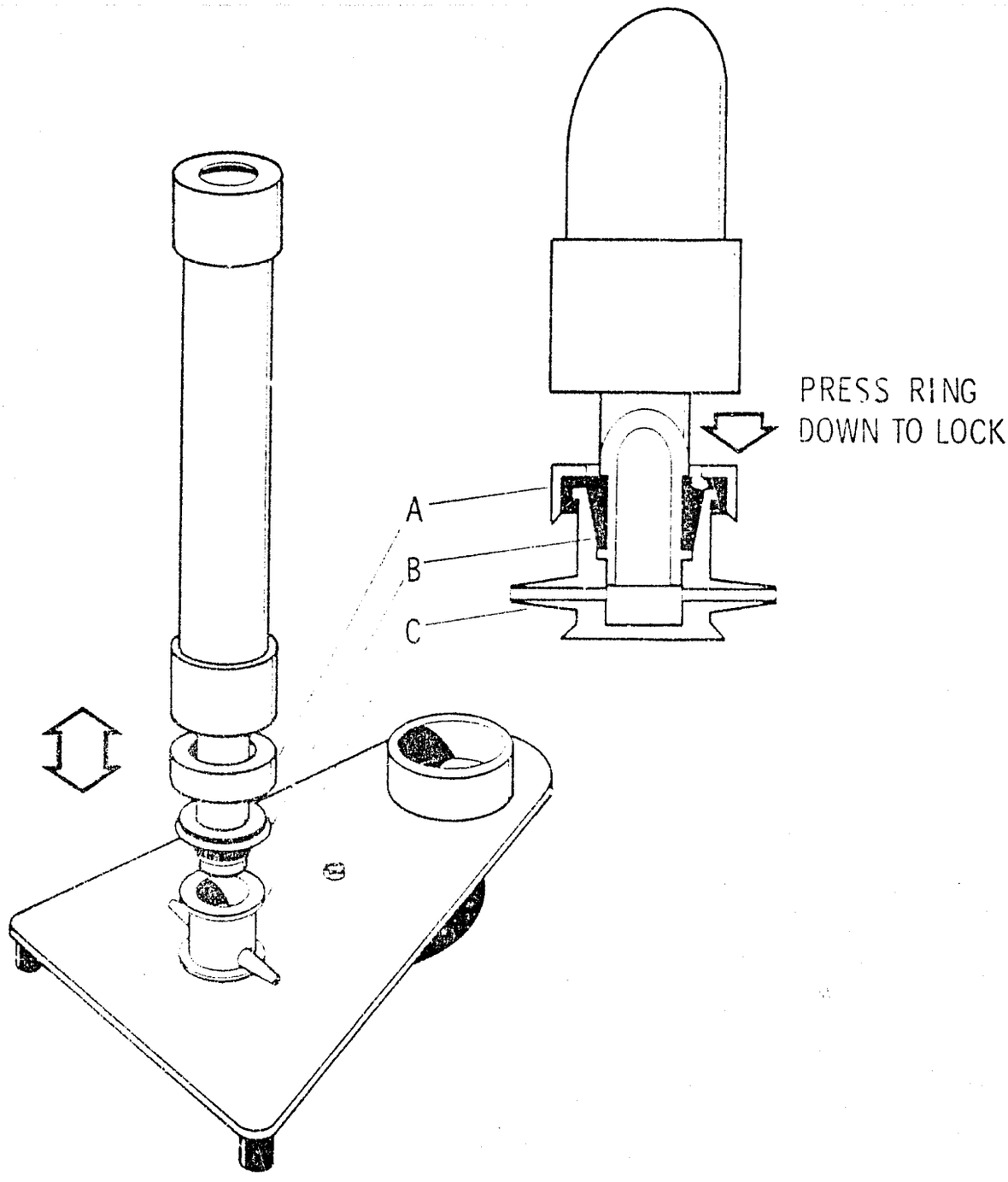



Figure 2

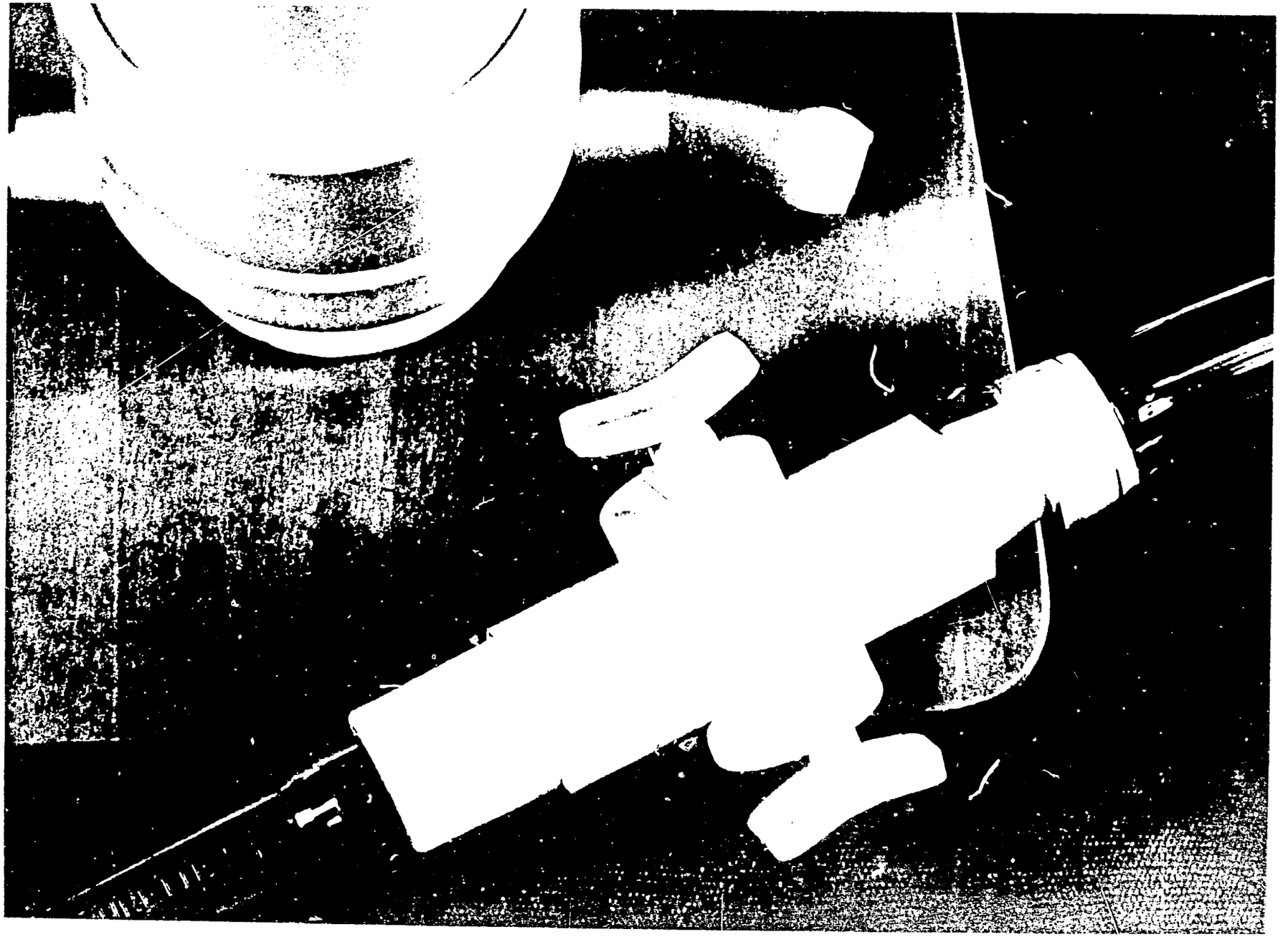
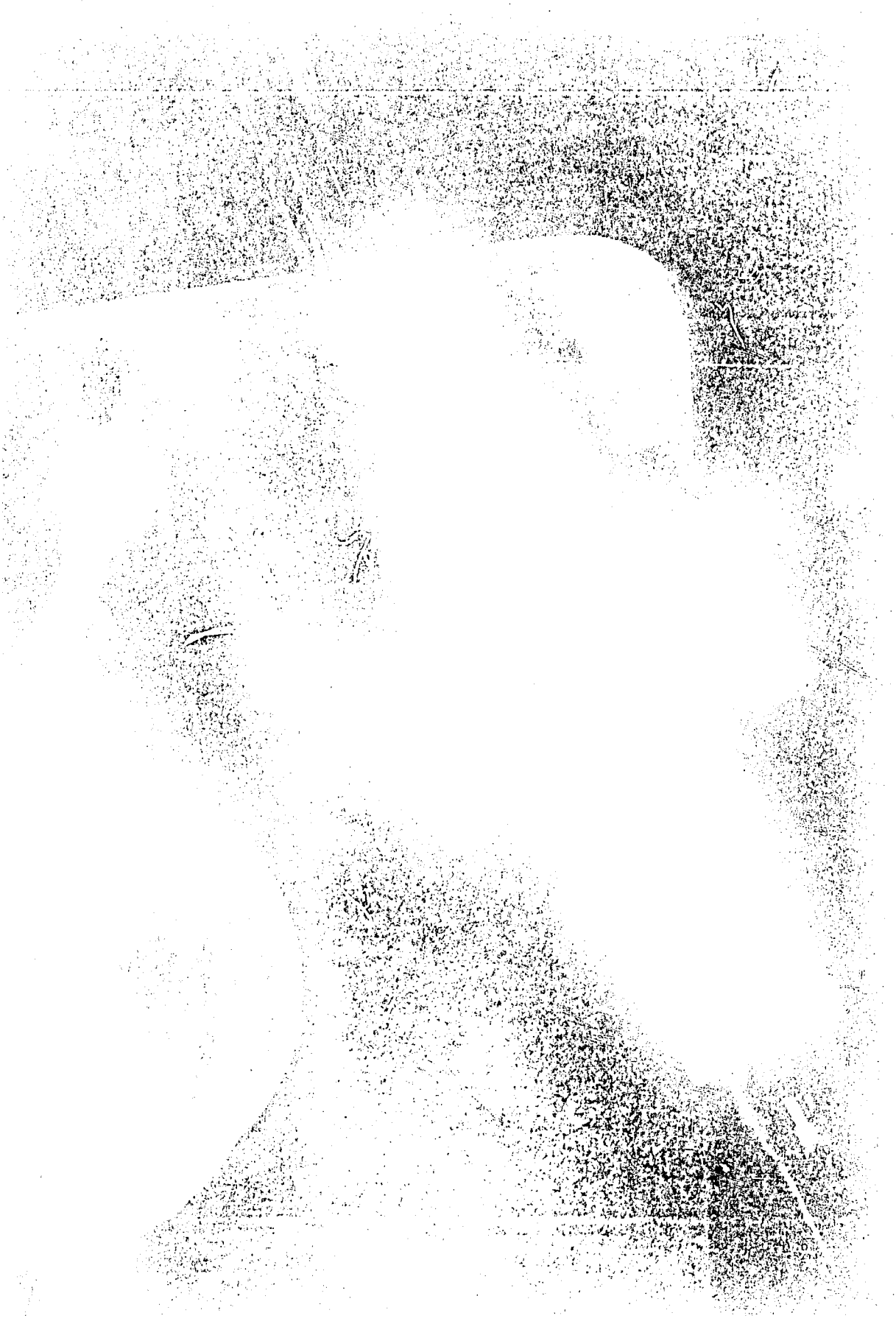


Figure 3a



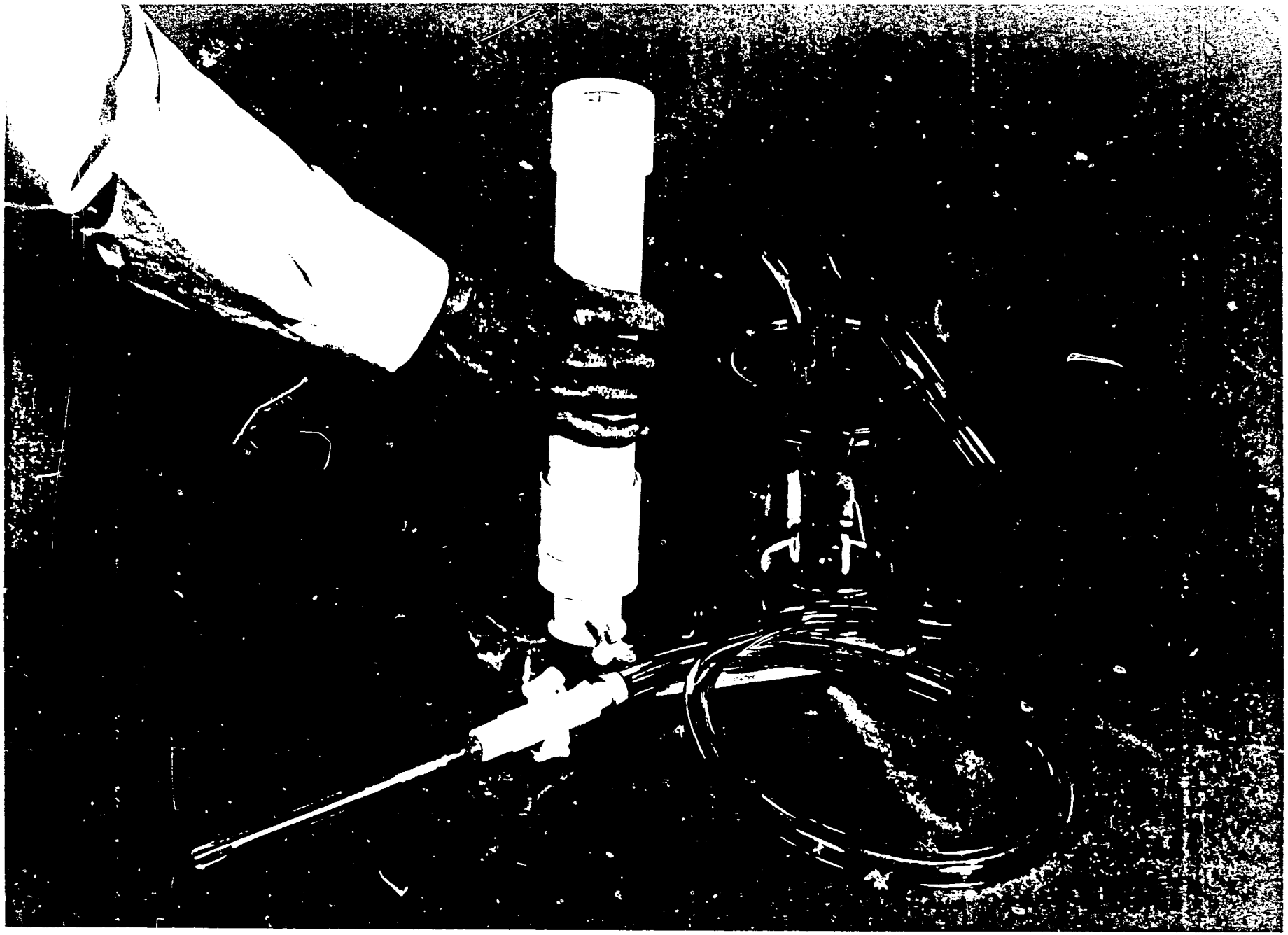


Figure 4b

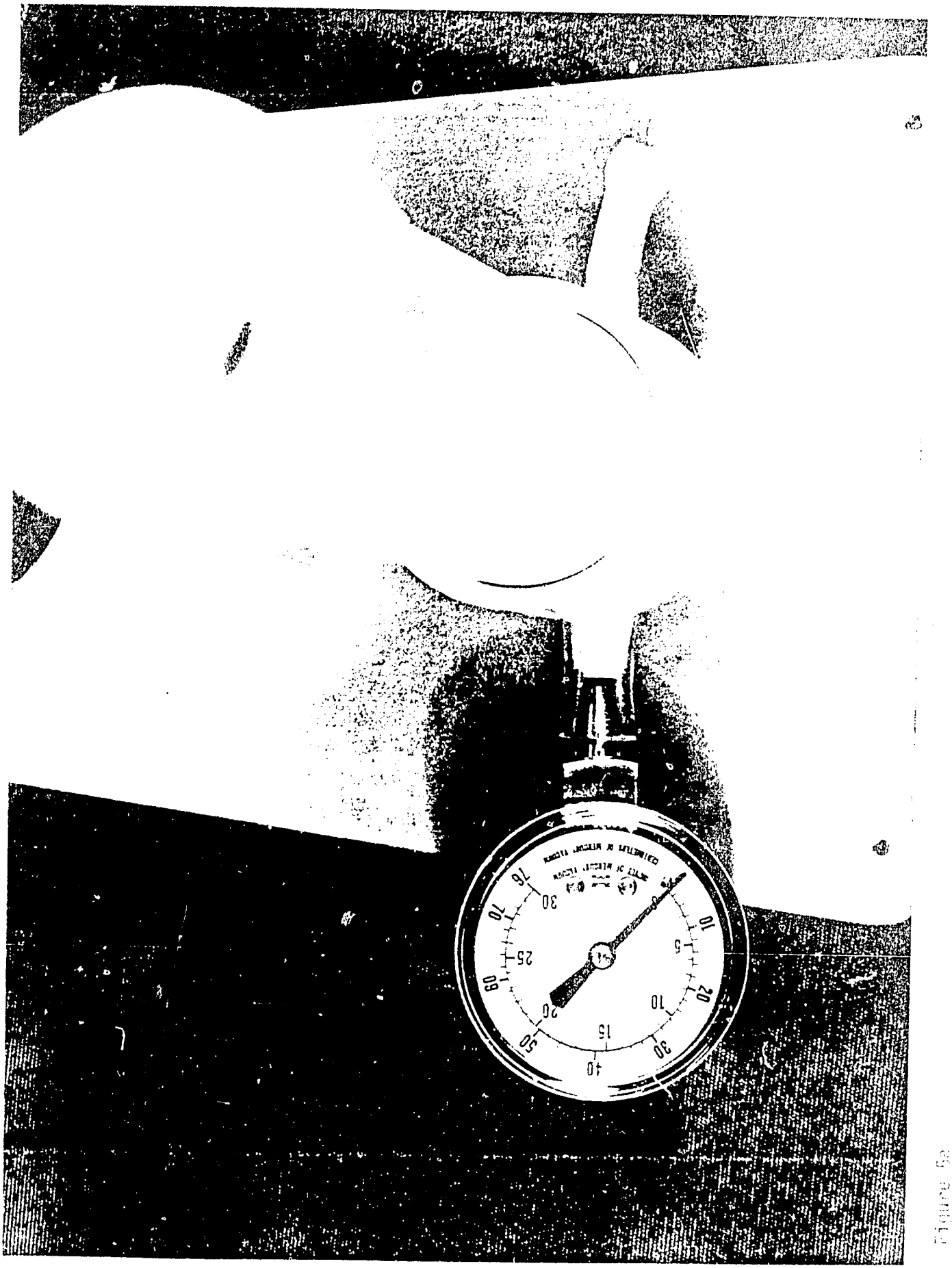


Figure 6a

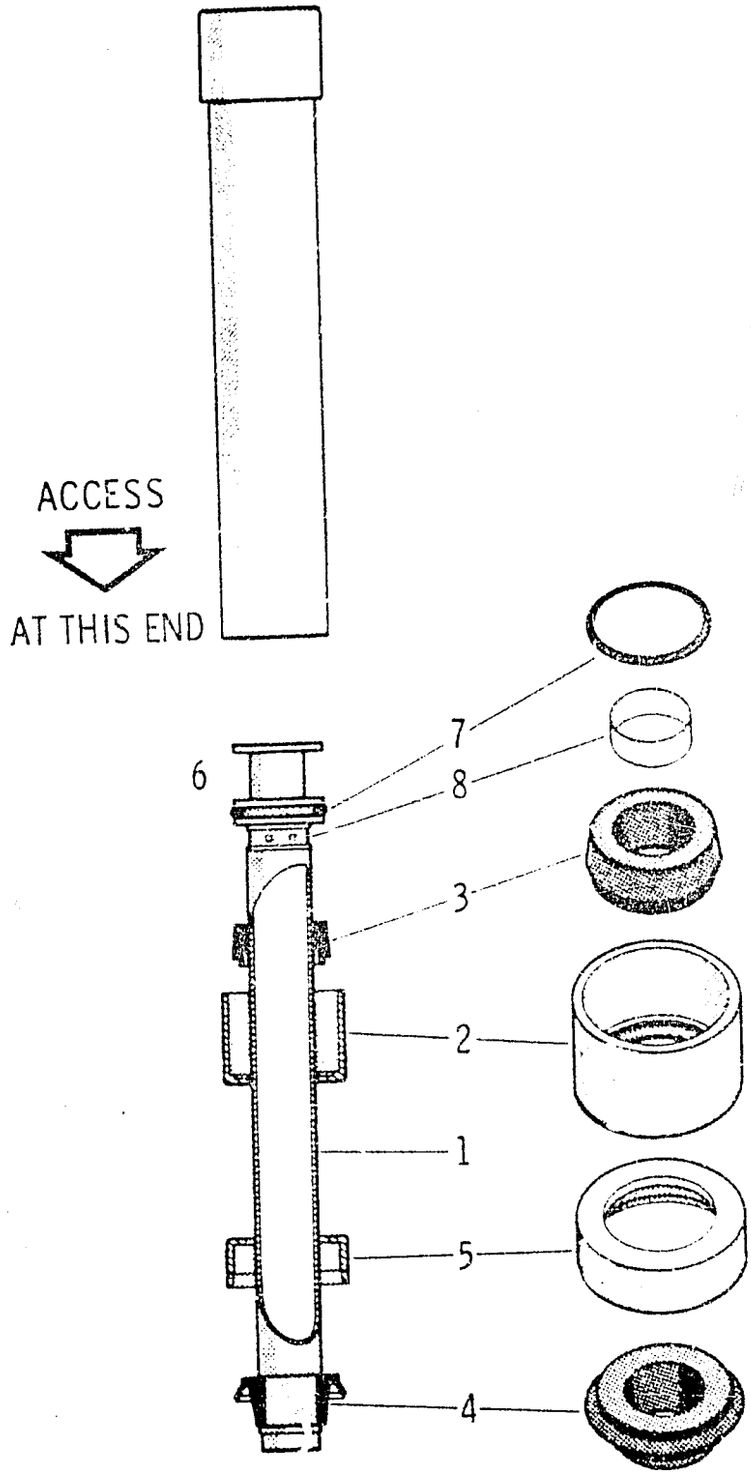



Figure 6

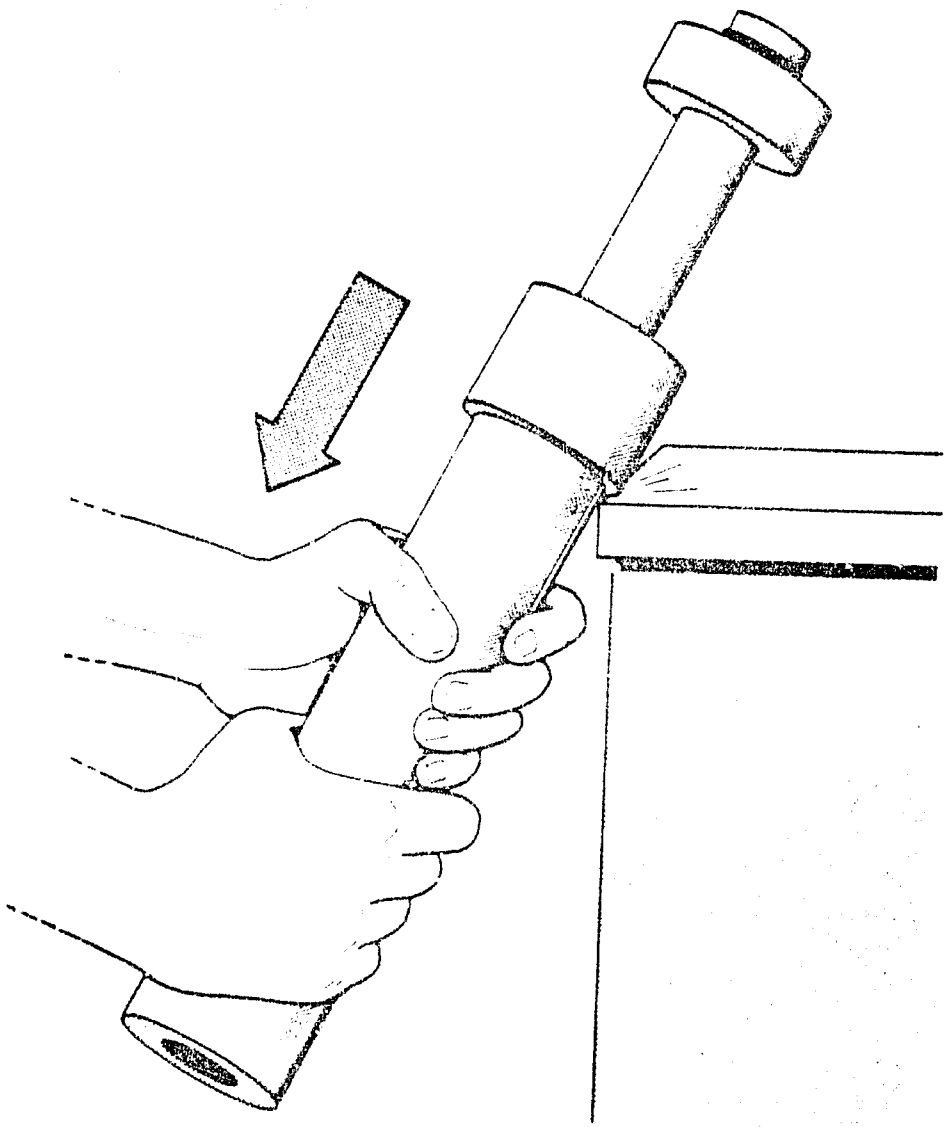


Figure 7

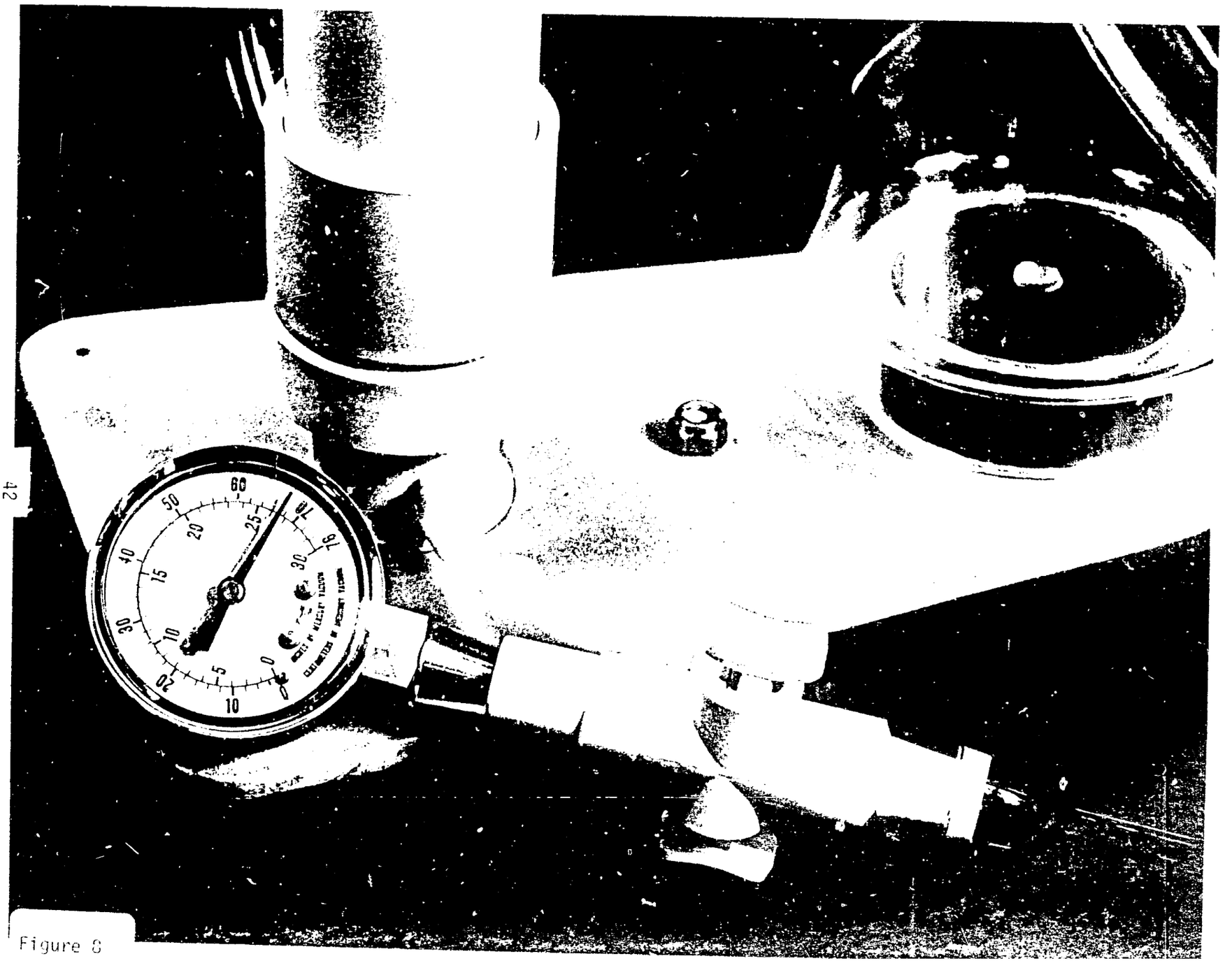
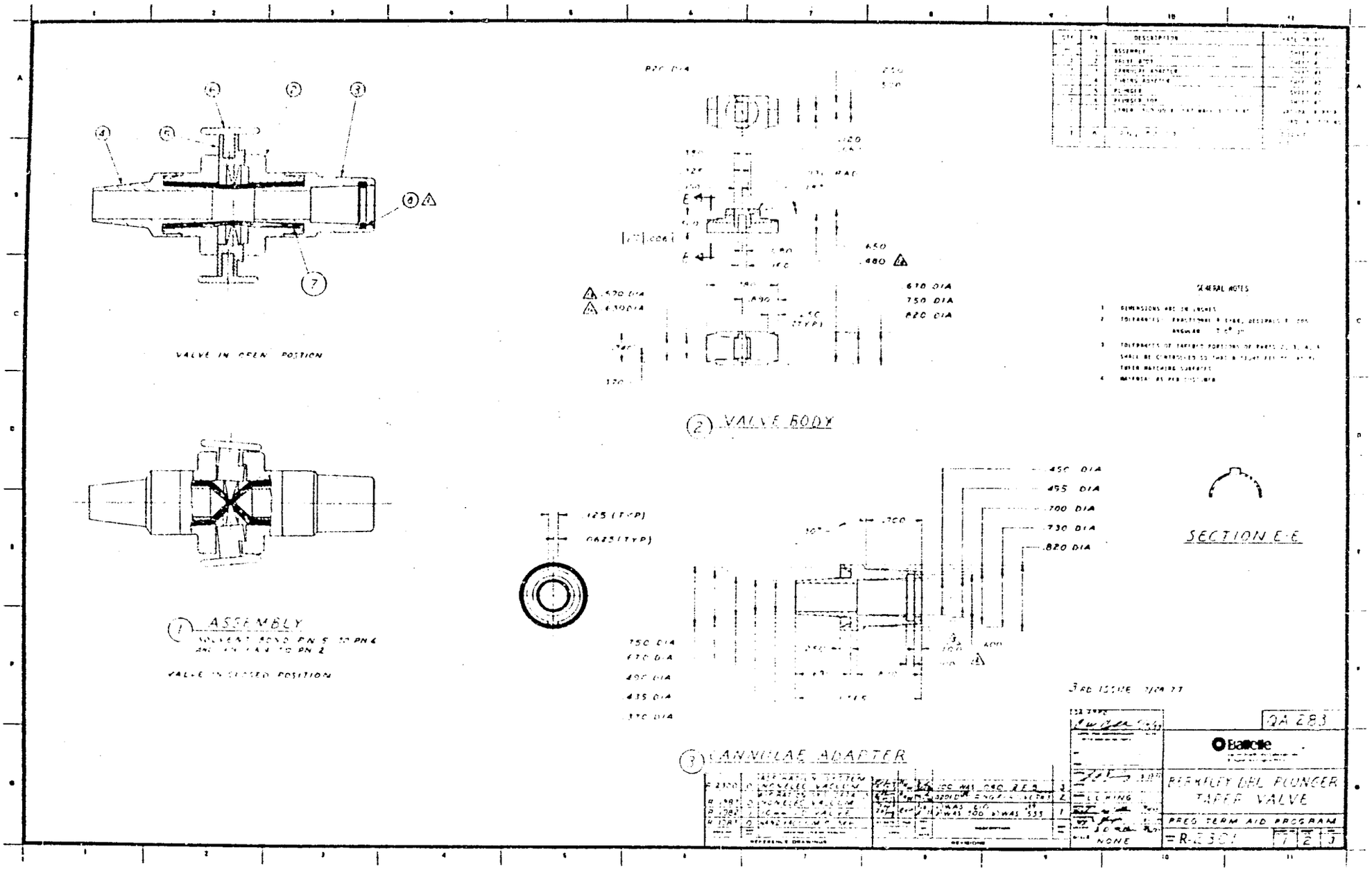
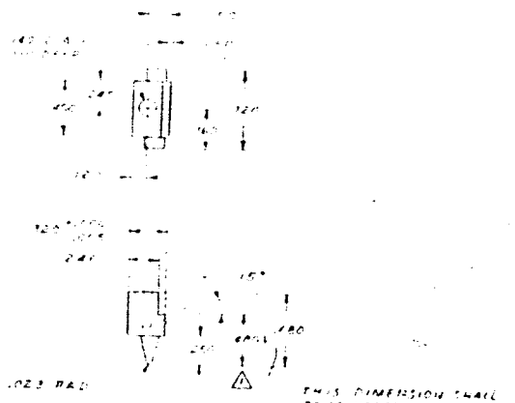
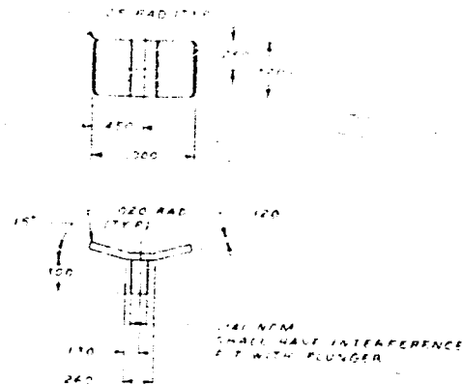



Figure 8

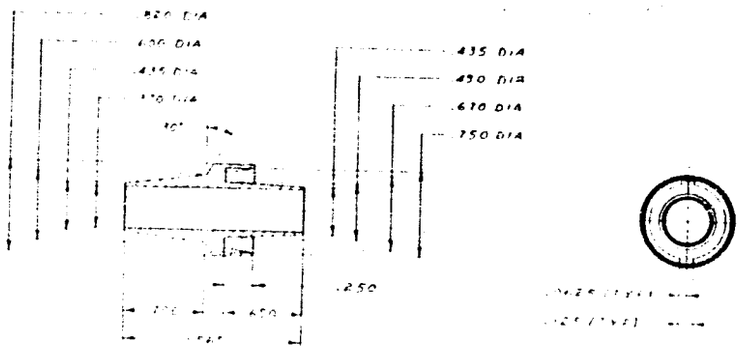

VALVE IN OPEN POSITION
2 VALVE BODY
1 ASSEMBLY
VALVE IN CLOSED POSITION
3 CANNULAE ADAPTER
SECTION E-E
GENERAL NOTES
3RD ISSUE
QA 283
Battelle
BERKELEY DBL PLUNGER TAPER VALVE
PREG TERM AID PROGRAM
NONE




(5) PLUNGER




(6) PLUNGER TOP




(4) TUBING ADAPTER

SEE ISSUE 2/28/73

QA 283

Battelle

BERKELEY DBL PLUNGER TAPER VALVE

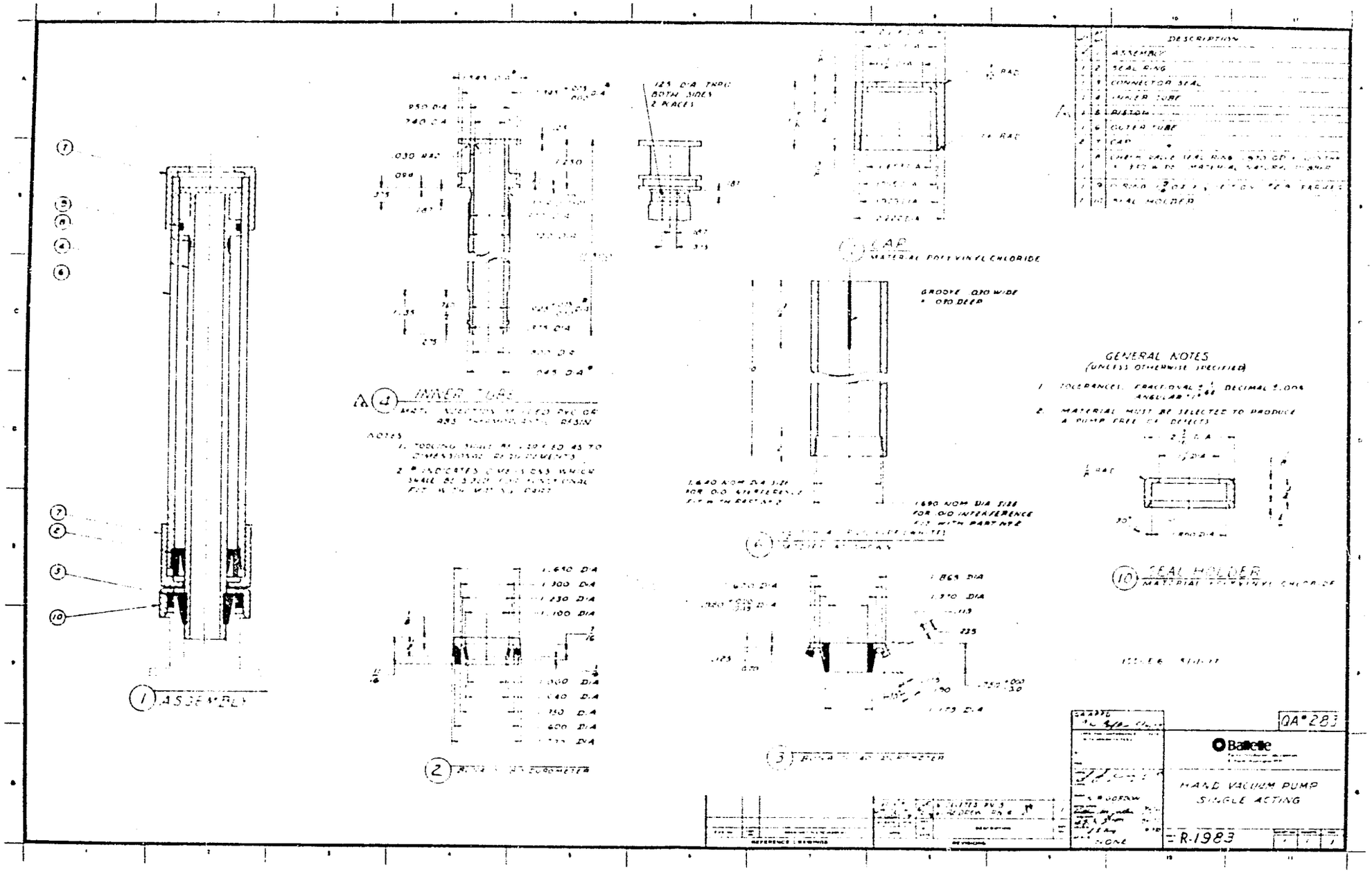
PREG TERM AID PROGRAM

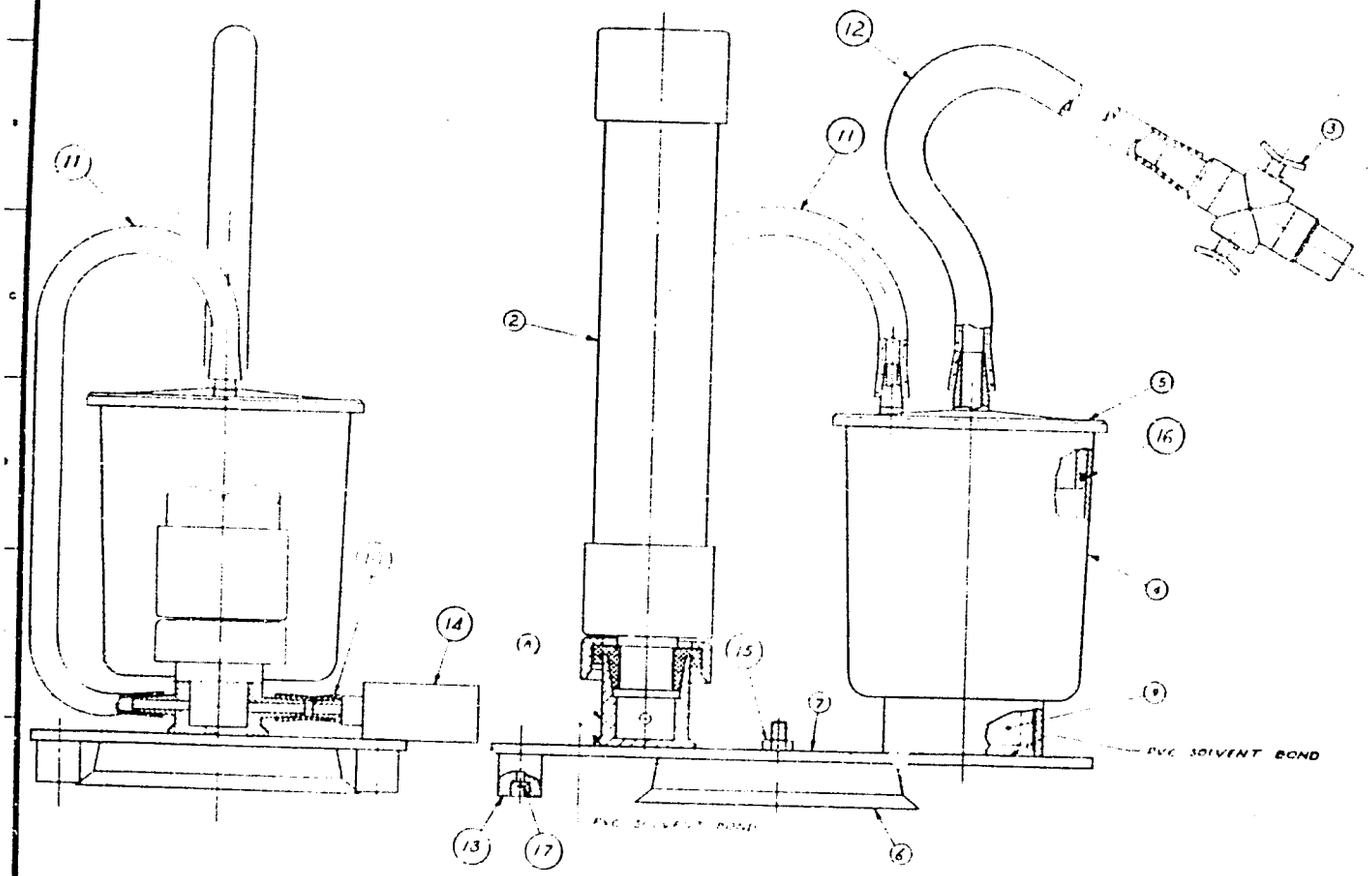
R-2301 | 2 | 2 | 1

NONE

REFERENCE DRAWINGS

REVISIONS


DESCRIPTION
ASSEMBLY
SEAL RING
CONNECTOR SEAL
INNER TUBE
PISTON
OUTER TUBE
CAP
SEAL HOLDER
1 ASSEMBLY
2
3
4 INNER TUBE
5 CAP
MATERIAL POLYVINYL CHLORIDE
GROOVE .010 WIDE
.010 DEEP
6
10 SEAL HOLDER
MATERIAL POLYVINYL CHLORIDE
GENERAL NOTES
(UNLESS OTHERWISE SPECIFIED)
1. TOLERANCES: FRACTIONAL ±1/64 DECIMAL ±.005
ANGULAR ±1/2°
2. MATERIAL MUST BE SELECTED TO PRODUCE
A PUMP FREE OF DEFECTS
Battelle
HAND VACUUM PUMP
SINGLE ACTING
QA*283
R-1983




1 ASSEMBLY

GENERAL NOTES

1. DIMENSIONS ARE IN INCHES
2. TOLERANCES: FRACTIONAL ±1/64, DECIMAL ±.005, ANGULAR ±1°
3. [illegible] IS 30 INCHES OF MINIMUM [illegible] WITH ADAPTOR TO ALLOW FOR [illegible] TUBE TUBING
4. [illegible] CHANGE [illegible]
5. [illegible]

2ND ISSUE 5/11/77

DRAWN [illegible]

| | | |
|---|---|---|
| R-2301 | 0 | TAPER VALVE BERKELEY BOL PLUNGER |
| R-1581 | 0 | ASPIRATION SYS DETAIL |
| R-1582 | U | NONELEC VACUUM |
| R-1583 | U | ICM-II VALVE |
| | | HAND VACUUM PUMP |

REFERENCE DRAWINGS

| | | |
|---|---|---|
| | | CONFIGURATION REVISED BASE & CONTAINER |

REVISIONS

LI KING

J.S. [illegible]

SCALE NONE

Battelle

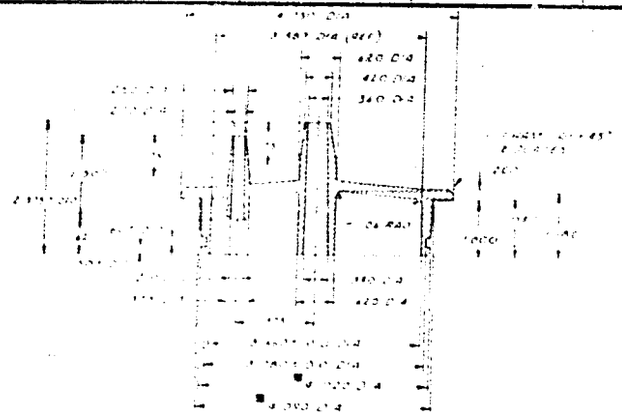
Q4-283

NONELEC VACUUM ASPIRATION SYSTEM

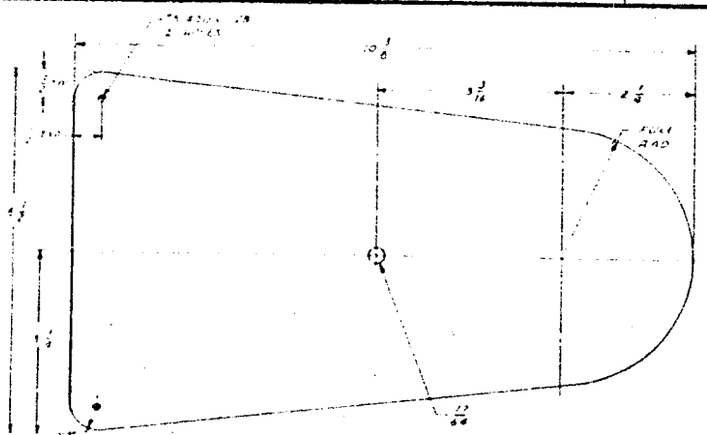
PREG TERM AID PROGRAM

R-2300

1 2 1

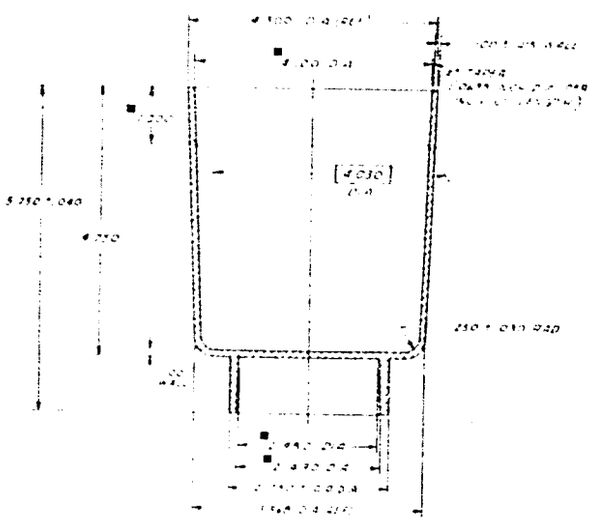


(5) MATL TRANSPARENT SECTION OF GLASS, THERMOPLASTIC

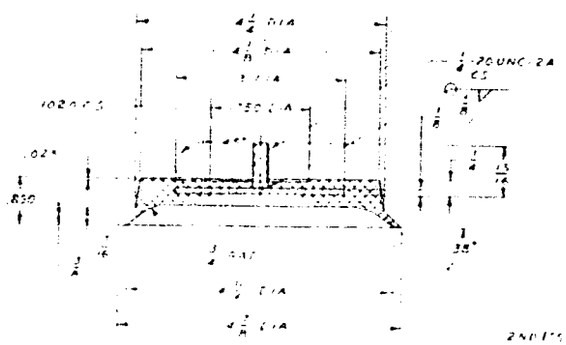


(7) BASE
MATL POLYVINYL CHLORIDE 3/16 THICK

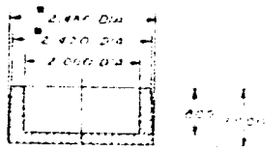
(8) PUMP BASE
MATL POLYVINYL CHLORIDE



(4) CONTAINER
MATL TRANSPARENT SECTION OF GLASS, THERMOPLASTIC



(6) SUCTION CUP
MATL NATURAL RUBBER 70 DUROMETER



(9) CONTAINER TOP
MATL POLYVINYL CHLORIDE

NOTES

1. ■ INDICATES DIMENSIONS WHICH SHALL BE CONTROLLED FOR FIT WITH MATING PART. THIS SHALL BE FUNCTIONAL SURFACE OF THE MOLDING

2ND PLUS SIDES

| | | |
|---|---|---|
| DATE | | |
| DRAWN | | |
| CHECKED | | |
| APPROVED | | |
| SCALE | NONE | |

Battelle

NONELEC AEROSOL ASPIRATION SYSTEM

PRES TERM AID PROGRAM

R-2300

REVISIONS

## SUMMARY COST STATUS ON AID/CSD-3152 PROJECT I

The following costs are provided from the Project Leader's printout of costs incurred. Such computer codes are used for continuing financial control during the course of the work. The figures provided below are not intended to replace the certified summaries of project costs provided by Battelle to the Contracting Officer, but rather are intended to provide the AID Technical Monitor with a brief summary of present status and funding remaining in the pipeline.

Week Ending 7-9-78

| | |
|---|---|
| Labor and Overheads | $262,631 |
| Materials and Subcontracts (consultants/tooling) | 48,737 |
| Travel | 18,615 |
| Facility and Equipment Use | 16,374 |
| Services (editorial, printing, graphics, etc.) | 6,198 |
| Fee | 22,195 |
| Total costs | 374,750 |
| Funds remaining | 32,506 |

Given known outstanding commitments on tooling and materials which have not yet been paid and the present level of effort by the contributions, we expect these funds to be used by September 30, 1978, when the contract period ends. A supplement of about $3,600 has not formally been added to the project, but it is expected that this will be placed into the accounting system in August. As we have discussed, additional funds will be directed toward transfer of technology activities.