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CONTRACT NASw-1621

**DESIGN FEASIBILITY STUDY OF STERILE
INSERTION TECHNIQUES
FINAL TECHNICAL REPORT**

OCTOBER 1967

Prepared for:

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
Washington, D.C.

N69-29736	(THRU)
(ACCESSION NUMBER)	(CODE)
92	31
(PAGES)	(CATEGORY)
6-101632	
(NACA CR OR TRX OR AD NUMBER)	

FACILITY FORM 602

MARTIN MARIETTA CORPORATION

DOCUMENT CHANGE INSTRUCTION

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Contract NASw-1621

DESIGN FEASIBILITY STUDY OF
STERILE INSERTION TECHNIQUES

FINAL TECHNICAL REPORT

October 1967

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FOREWORD

The Martin Marietta Corporation Denver Division submits this final report of the design feasibility study of sterile insertion techniques as required by Article VIII-C, Contract NASw-1621. This report is in a single volume.

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SUMMARY

The objective of this study was to develop a number of design concepts for sterile insertion. These concepts use heat sealing of plastic films to permit aseptic penetration of a container with a sterilized interior. For future applications, the container may represent anything from a space probe to a large spacecraft that requires repair, modifications, or additions after terminal sterilization. The sterile insertion operation must be performed with a very low probability of compromising the sterility of the spacecraft interior.

The study had two major portions; one was devoted to the development of the design concepts for the sterilization canister entry port, the service bag, and the heat-sealing and cutting tools; the second was devoted to the materials evaluation and selection of the plastic film for use as the barrier over the entry port.

As a result of this study, six feasible design concepts for sterilization-canister entry ports, with corresponding service bags and service-bag mounting methods, were conceived. Three concepts used external plastic barriers; three (including the final recommended design) employ internal plastic barriers. In addition, four designs for heat-sealing tools and five designs for cutting tools were evolved.

The heat-sealing tools applied the concepts of:

- 1) A self-propelled caterpillar;
- 2) A manually operated wheel;
- 3) A single stationary ring type;
- 4) A double stationary ring type.

The cutting tools applied the concepts of:

- 1) A self-propelled rolling blade;
- 2) A powered blade;
- 3) A manually operated rolling blade;
- 4) A manually operated rolling tool with a hot wire incorporated in the wheel;
- 5) A ring type to be used with the ring-type heat-sealing tools.

The materials portion of this study was divided into a screening test effort and a physical properties test effort. The screening tests were performed on all candidate materials, while the remainder of the physical properties testing was limited to those candidate materials that successfully passed the screening tests.

Screening tests determined compatibility of the candidate materials with the ethylene oxide/Freon 12 (12%/88%) mixture and the dry-heat sterilization cycle of 125°C for 24.5 hours. The physical properties tests of the materials that passed the screening tests included sealability, fusion, sterilization resistance, seam strength, burst strength, transparency, formability, flexibility, and film-attachment tests.

As a result of this study, Design Concept A for the sterilization canister entry port and its corresponding service bag was recommended. This concept employs an internal plastic barrier, a self-propelled heat-sealing tool, and a self-propelled cutting tool. FEP teflon with a thickness of 0.005 inch (5 mil) was the candidate plastic film recommended for the barrier.

I. INTRODUCTION

Interplanetary missions contemplated for Mars and Venus will require highly sophisticated unmanned spacecraft. These spacecraft must be sterilized to carry out their life-detection missions, and to conform to international policies for planetary exploration that forbid the contamination of the planets by terrestrial microorganisms. Terminal heat sterilization under conditions equivalent in biological kill effect to a temperature of 125°C (257°F) for 24.5 hours is the only NASA-approved method of sterilizing spacecraft. Functional failures after this treatment presently require a repetition of the heat cycle after repairs are accomplished. The time required for this repetitive treatment, coupled with the uncertainty of maintaining a completely operable system, could jeopardize launch during the available launch period, which occurs only once every two years. In addition, specific items such as batteries, tape recorders, and heat-sensitive scientific payloads may not be terminal-heat sterilizable. To solve these problems, a reliable sterile insertion technique is required.

A possible solution to the sterile insertion problem is based on application of gnotobiotic techniques originally developed for raising germ-free animals. Recognizing the potential merit of this technology, NASA awarded Martin Marietta Corporation, Denver Division, a contract (NASw-1407)* to determine the feasibility of using gnotobiotic insertion techniques for sterile assembly and repair of spacecraft. Feasibility was demonstrated using a laboratory test apparatus consisting of flexible film isolators with attendant filters, traps, etc., developed for raising germ-free animals. In demonstrating feasibility, sterile parts were transported through an area of intense biological contamination into a sterile environment without destroying the sterility of the component or the sterile environment.

During this preliminary study, specific areas requiring development for spacecraft application became apparent. These areas are discussed briefly below:

Sterilizable Materials Availability - Repeated exposure to ethylene oxide exhibited a degrading effect on the physical properties of the plastic isolators, particularly on the thin-film extended-glove bag. These films are also known to be incompatible with dry-heat sterilization. Accordingly, materials without these shortcomings are required before an acceptable technique can be evolved.

*Martin Marietta Corporation Final Report; Contract NASw-1407; "Investigation of the Reliability of Sterile Insertion Techniques for Spacecraft"; October 1966.

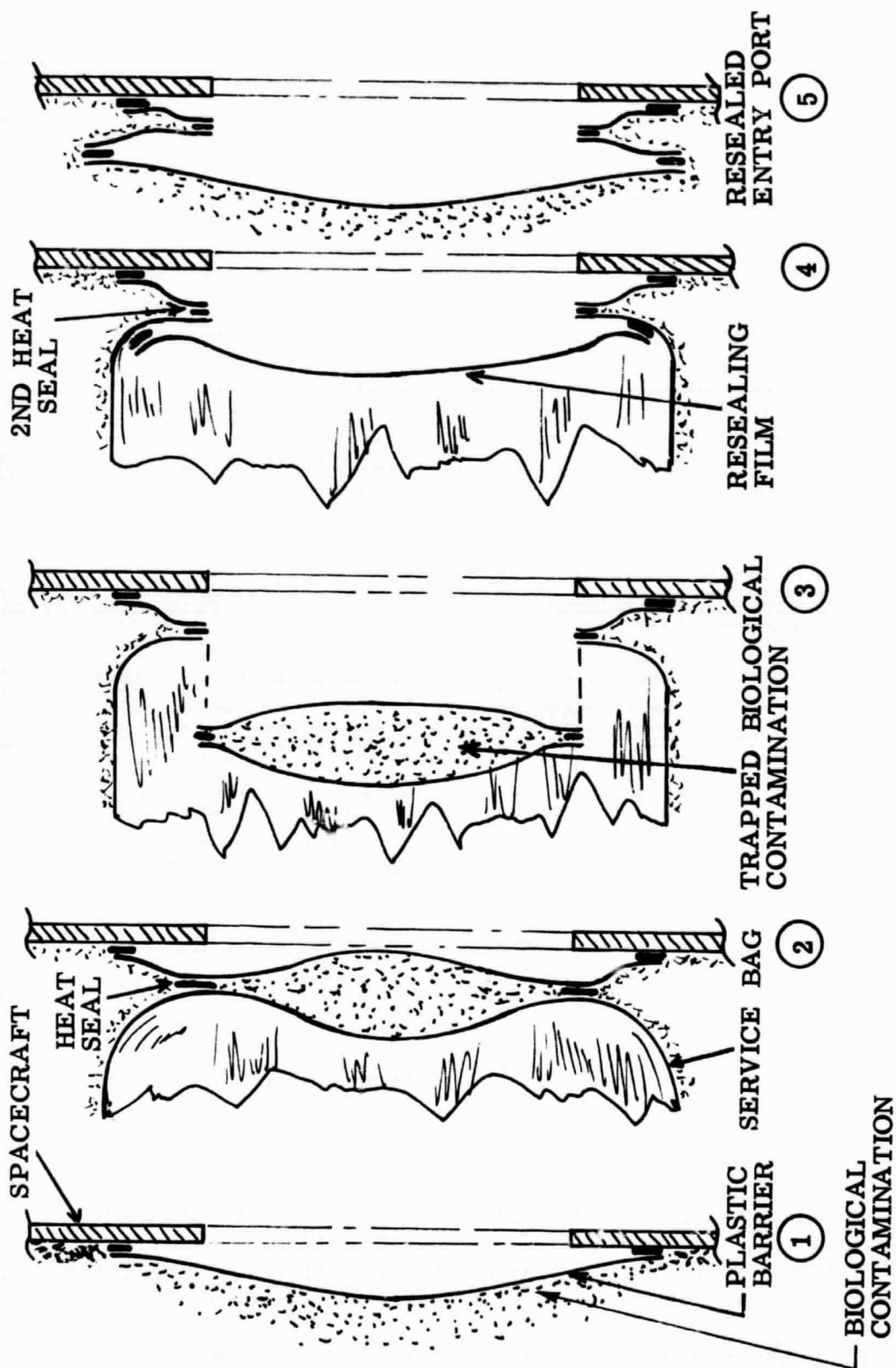


Fig. I-1 General Concept for Sterile Insertion

Practical Application to Spacecraft - Present gnotobiotic sterile insertion techniques cannot be applied directly to spacecraft because operations from the isolator side (i.e., inside the spacecraft) are normally part of the sterile insertion sequence. However, modifications of these basic gnotobiotic concepts may prove adaptable for spacecraft applications and would warrant investigation.

Martin Marietta* developed an adaptation of gnotobiotic techniques based on a heat sealing of a plastic biological barrier to the service bag. This concept operates as follows (Fig. I-1):

- 1) The sterilization canister entry port is covered by a plastic barrier.
- 2) The service bag is heat sealed to the plastic barrier to encase the exterior biological contamination on both surfaces inside the sealed disc.
- 3) Cutting through the center line of the seam and removing the center disc provides access to the spacecraft interior.
- 4) Resealing is accomplished by heat sealing a sterile replacement barrier over the entry port.
- 5) The service bag is cut away to return the entry port to the original plastic-barrier-covered configuration.

Further investigation of this adaptation of gnotobiotic techniques appeared to offer great promise of development of practical designs. A program was therefore instituted under NASA Headquarters sponsorship to develop alternative designs with a concurrent program to evaluate candidate plastic materials for use with these designs.

Factors considered in the development of the design concepts included reliability, safety, cost, ease of operation, ease of manufacture, weight penalty, and time required for operation. The materials evaluation program recognized the anticipated design requirements for ethylene oxide/Freon 12 compatibility, dry heat sterilization compatibility, membrane burst strength, fusion characteristics, flexibility, seam strength, transparency, film strength, and film attachment adhesion to the periphery of the sterilization-canister entry port.

The results of these investigations are described in this report. Chapter II covers the design concepts, Chapter III reports on the materials evaluation, and Chapter IV provides conclusion and recommendations, with supporting data in the appendixes.

*Invention disclosure by A. A. Rothstein, L. Edelstein, and L. J. Sullivan, Docket 66YD35, Method of Sterile Replacement or Repair of Spacecraft by Heat Sealing Plastic Surfaces."

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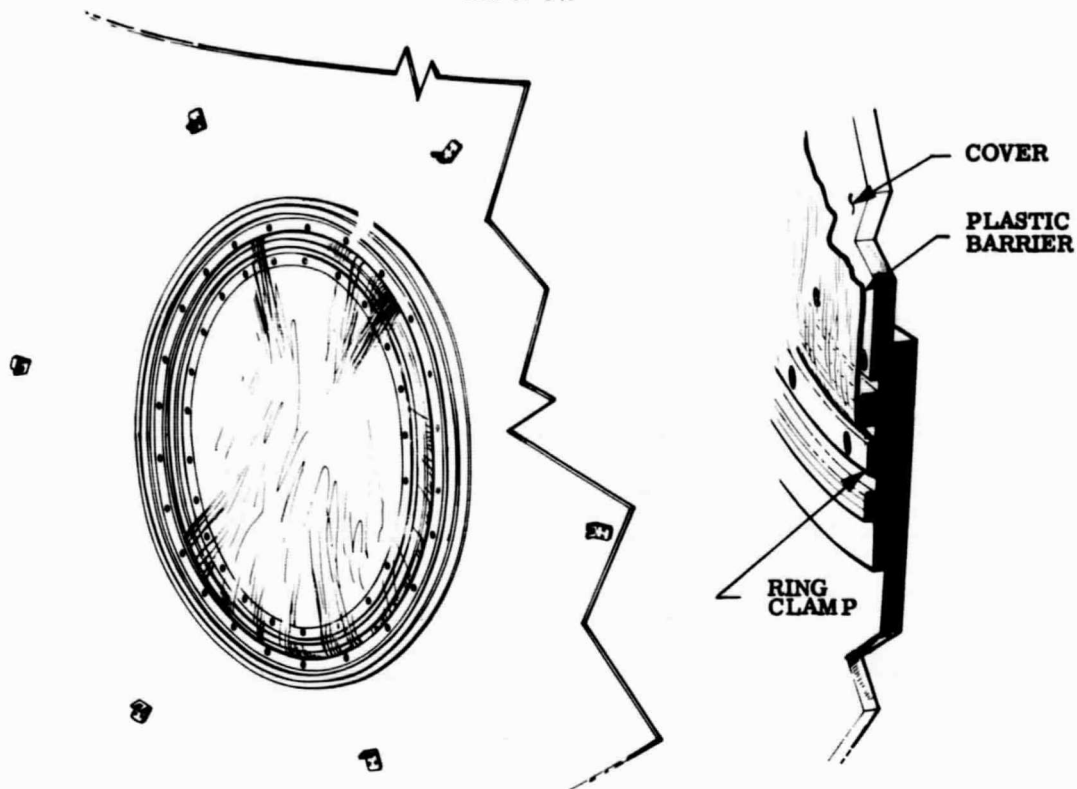


Fig. II-1 Design Concept 1, Bond and Clamp

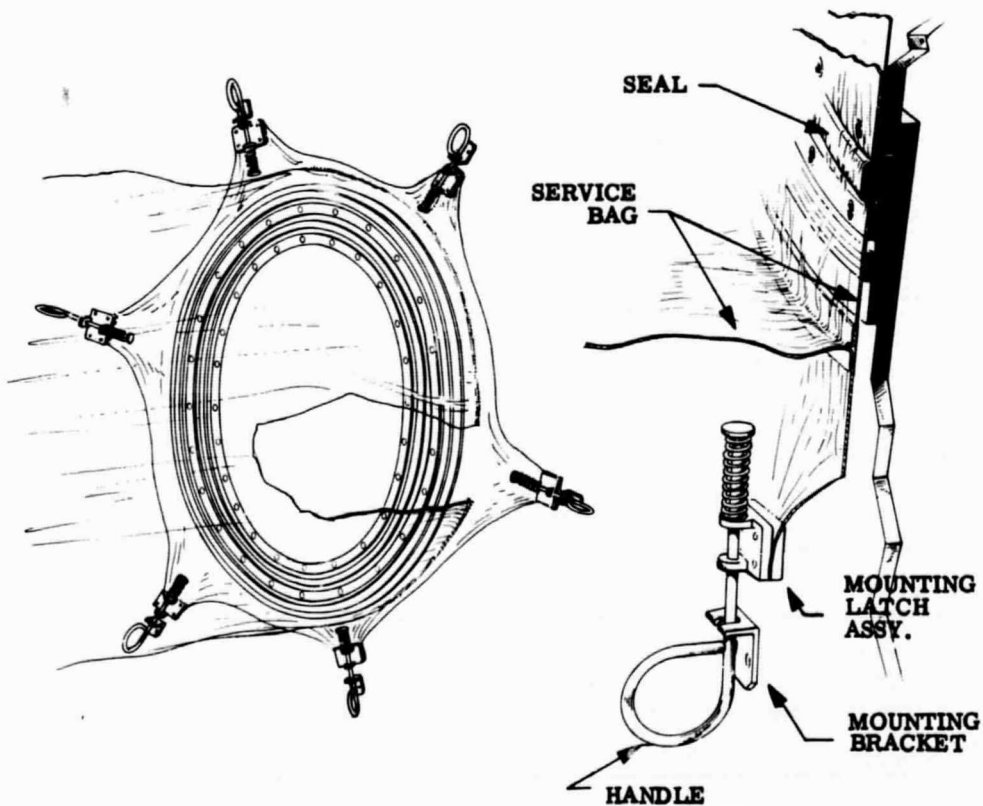


Fig. II-2 Design Concept 1, Service Bag

II. DESIGN CONCEPTS

A. PRELIMINARY DESIGN CONCEPTS

This section describes the four preliminary design concepts developed in the initial phase of the program. These designs were the subject of the Design Review Meeting discussed in Section IIB. All concepts are sized for an 18-inch diameter entry port. This uniform entry diameter was chosen to provide design uniformity and a sizing suitable for evaluation as a working model. Emphasis was placed on alternative design approaches to:

- 1) Port closure;
- 2) Plastic bio-barrier attachment;
- 3) Service bag positioning;
- 4) Heat sealing and cutting surfaces;
- 5) Heat sealing tools;
- 6) Cutting tools;
- 7) Resealing plastic positioning.

These alternatives are described for each design concept in the following subsections.

1. Design Concept 1

Design concept 1 uses an external plastic barrier bonded and clamped around the entry port (Fig. II-1). The service bag (Fig. II-2) is provided with six spring-loaded mounting-latch assemblies that hook to special mounting brackets and spread the bag over the entry port. The bag is heat sealed to the plastic barrier at the heat-sealing surface. All heat-sealing surfaces are coated to prevent the plastic barrier from sticking to the sealing surface. The ensuing seam is 5/8- to 3/4-inch wide. The heat sealing surface is raised, offering a guide rail for the heat-sealing tool and some control of the amount of compression of the two layers of plastic film. A cut is made through the centerline of the seam (Fig. II-3), and the center disc removed. This disc consists of the two circular pieces of plastic, sealed at the periphery with their biologically contaminated surfaces trapped between them.

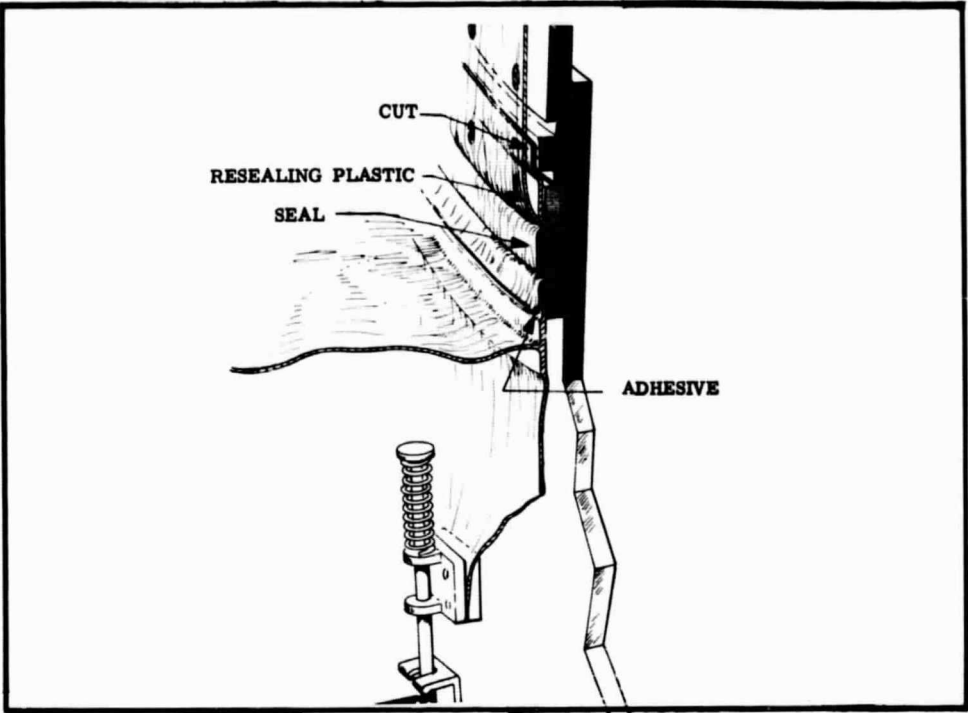


Fig. II-3 Design Concept 1, Seam Cut

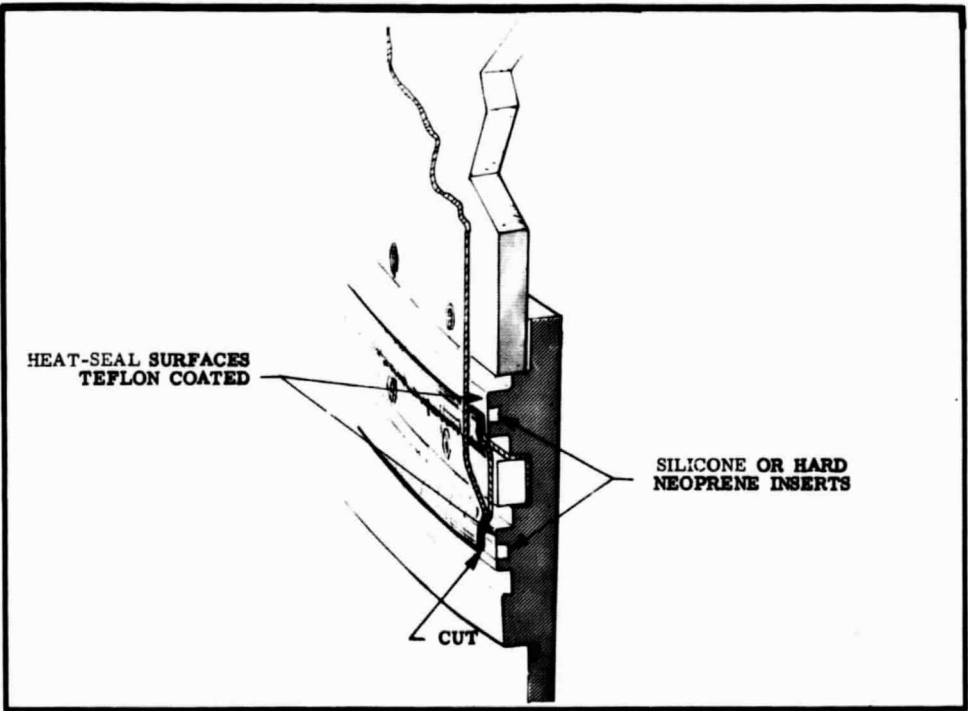


Fig. II-4 Design Concept 1, Resealing Seam Cut

The sterilized entry port cover is removed and placed inside the bag. The cover is replaced after completion of the required service. A sterilized circular resealing plastic sheet inside the bag is fastened to the service bag. To facilitate fastening, the resealing plastic is provided with pressure-sensitive adhesive tape at its periphery. The resealing plastic is then heat sealed to the service bag at the resealing surface. This surface is identical in shape and size to the sealing surface and provides the same seam width. The sealing and resealing surfaces are provided with asbestos or hard silicone inserts for cutting-tool protection. The resealing seam is cut through the centerline (Fig. II-4), and the service bag with its mounting latches and brackets is removed.

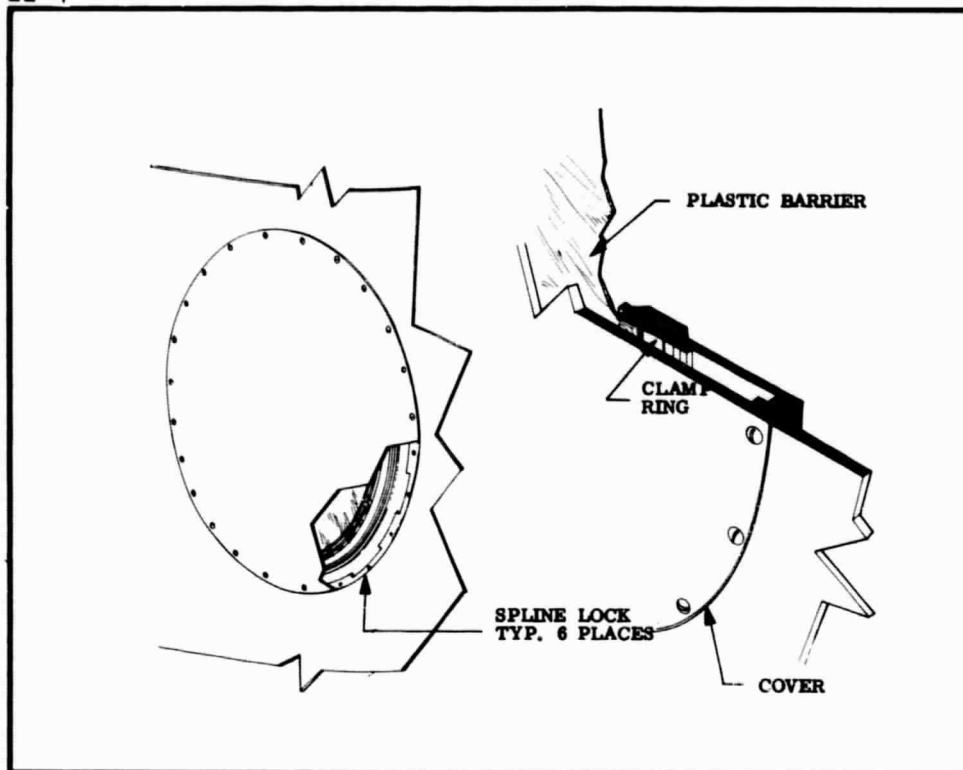


Fig. II-5 Design Concept 2

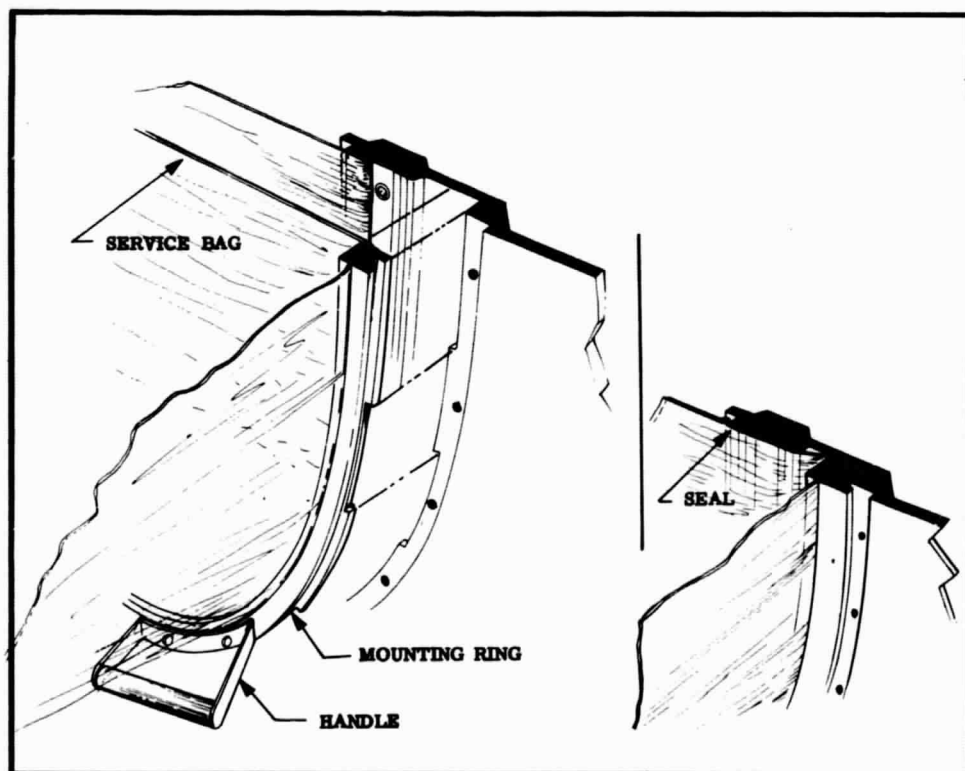


Fig. II-6 Design Concept 2, Service Bag Mounting Ring

2. Design Concept 2

This concept uses an internal plastic barrier (Fig. II-5). The entry port cover is therefore exposed to biological contamination and is removed before the start of the sterile insertion procedure. The plastic barrier is fastened around the 18-inch diameter port by the bond and clamp method of Design Concept 1. The service bag is provided with a mounting ring that locks to the entry port by splines. The splines engage corresponding splines machined in the frame around the port (Fig. II-6). A few degrees of rotation at the two external handles is sufficient to lock the ring in position. Heat sealing of the service bag to plastic barrier is similar to Design Concept 1. The surfaces are designed with a guide edge on one side only. The ensuing seams are 5/8- to 3/4-inch wide. The center disc is cut away, exposing the open port (Fig. II-7). After completion of the required service, the resealing plastic with preformed dished-in periphery is fastened in position by adhesive tape to the inner side of the mounting ring and heat sealed to the service bag. The resealing seam is cut through the centerline (Fig. II-8). The service bag mounting ring is unlocked by rotating it in the opposite direction, and removed, leaving the resealing plastic as replacement for the original plastic barrier. The entry port cover is replaced and bolted in position.

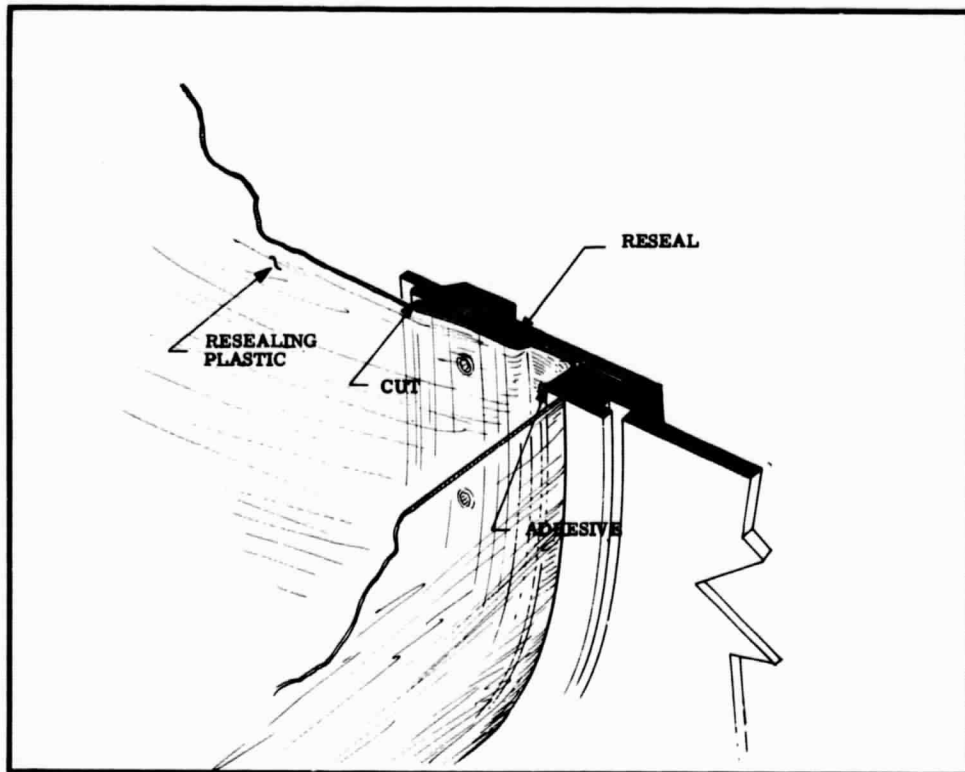


Fig. II-7 Design Concept 2, Cut to Expose Port

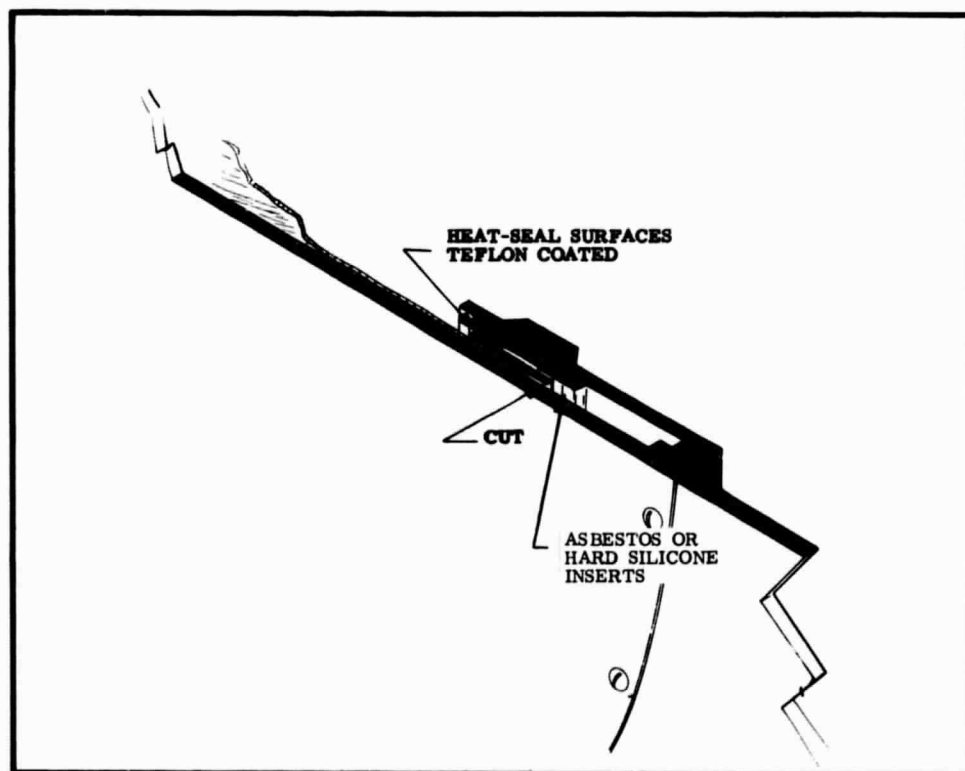


Fig. II-8 Design Concept 2, Resealing - Seam Cut

3. Design Concept 3

Design Concept 3 (Fig. II-9) uses an external plastic barrier that is bonded and clamped to the extended entry-port frame by a radial clamp ring. The ring may consist of two or more segments to allow for better loop pressure at the bonding surface along the circumference. The service bag has a preformed base with a mounting skirt. The skirt is fastened to the extended service-port frame by an elastic cord (Fig. II-10) outside the service bag. A groove is machined in the frame to accommodate the cord and prevent it from sliding off. The heat-sealing surfaces have only one guide edge. The service bag is heat sealed to the plastic barrier. After cutting the seam, the resulting center disc is removed (Fig. II-11). The service-port cover is removed and replaced after performing the necessary work. The preformed re-sealing plastic is fastened to the cylindrical surface of the clamp ring by an elastic cord identical to the cord used to fasten the service bag. The cord fits into an identical groove machined into the cylindrical surface on the periphery of the clamp ring. This cord, however, is located inside the service bag. The re-sealing plastic is heat sealed to the service bag. The flat surface of the clamp ring serves as the resealing surface. A cut is made through the centerline of the resealing seam (Fig. II-12). The two elastic cords, the service bag, and the periphery of the resealing plastic are removed, leaving the resealing plastic as replacement for the original plastic barrier.

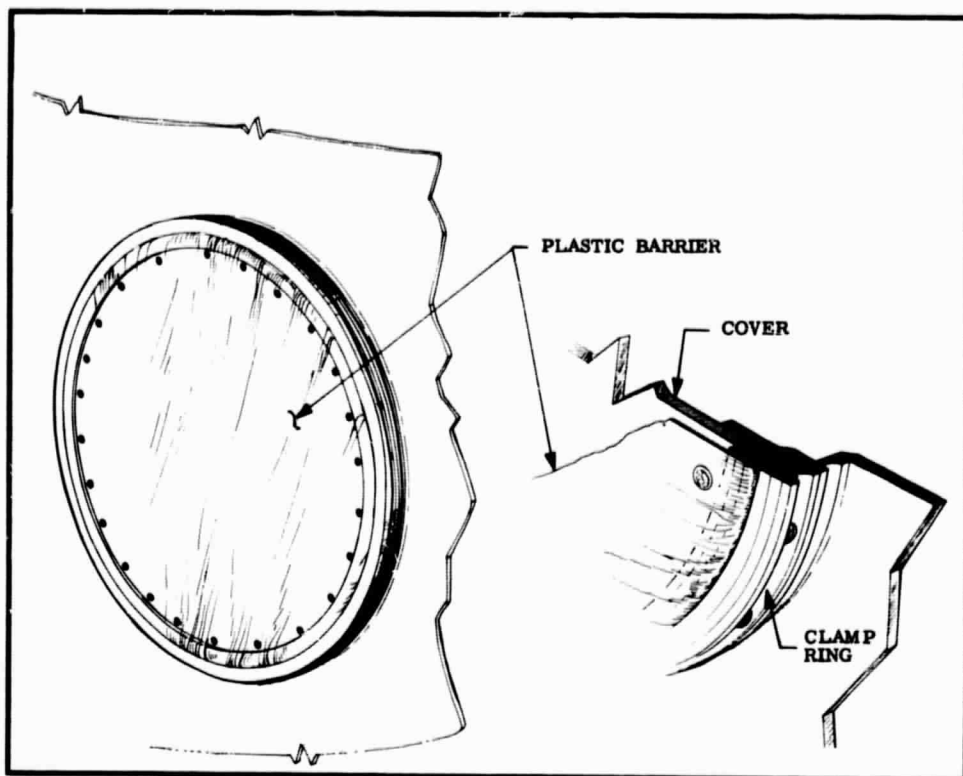


Fig. II-9 Design Concept 3

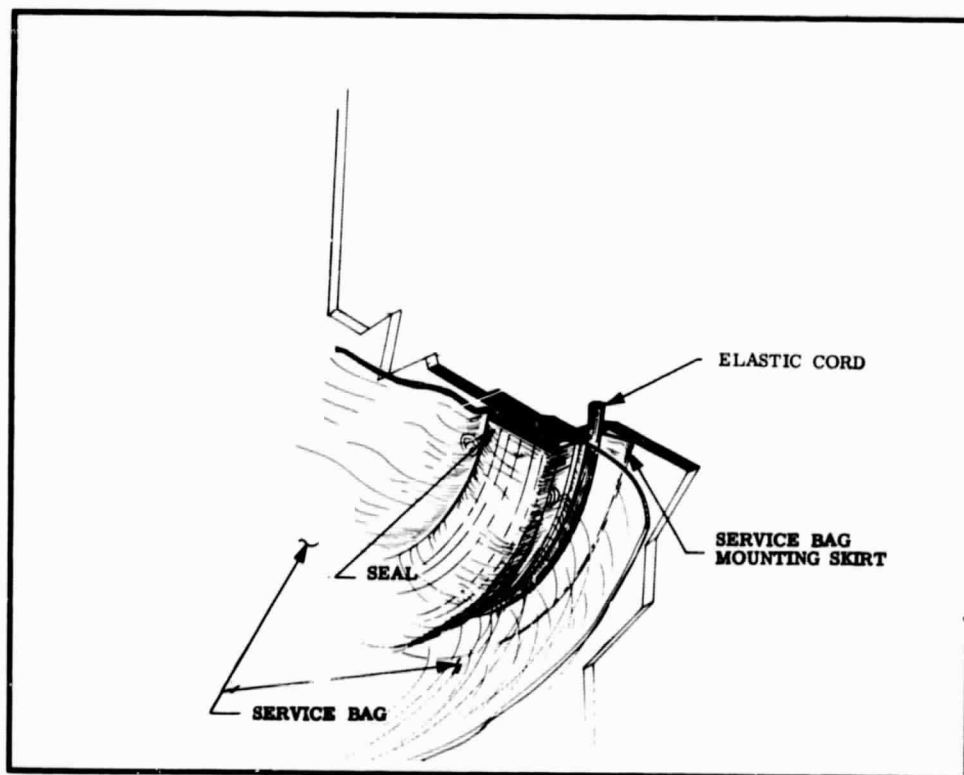


Fig. II-10 Design Concept 3, Elastic Cord Installation

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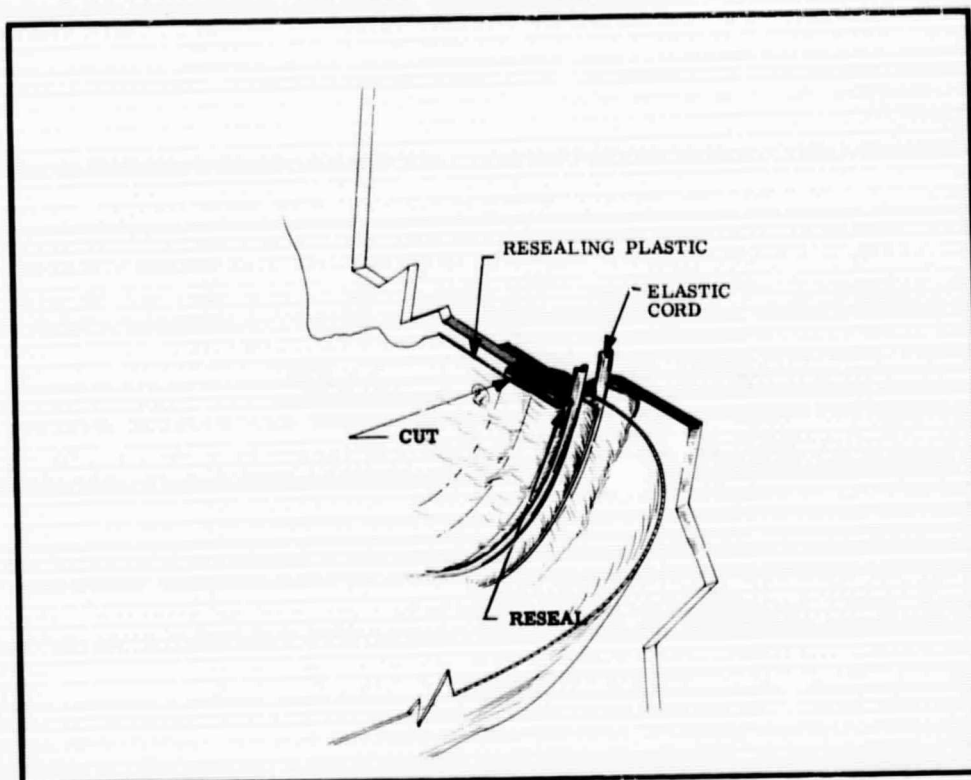


Fig. II-11 Design Concept 3, Cut for Access to Service Port

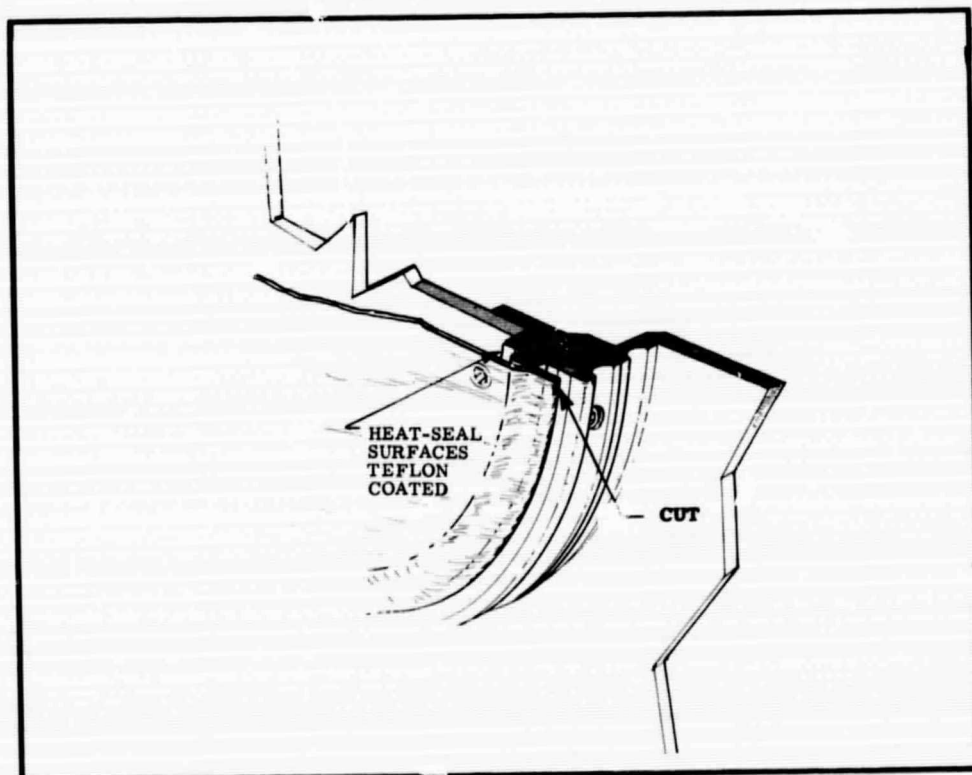


Fig. II-12 Design Concept 3, Cut in Resealing Seam

4. Design Concept 4

This concept also uses an external plastic barrier (Fig. II-13). The barrier is bonded and clamped in the same manner as Design Concepts 1 and 2. Design Concept 4 uses grooved sealing and resealing surfaces with a cutting wire or cutting blade mounted at the bottom of each groove. The service bag (Fig. II-14) is similar to the service bag for Design Concept 1. The six spring-loaded mounting latches of Design Concept 1 are replaced by six suction cups. These two service bag designs are in fact interchangeable. Heat sealing the service bag to the plastic barrier and cutting through the centerline of the seam is done in one operation. Following the general sequence of operations, the center disc is removed (Fig. II-15), all service performed and the opening resealed by the resealing plastic. Resealing and cutting is done, as before, in one operation. The service bag is then removed from the entry port (Fig. II-16).

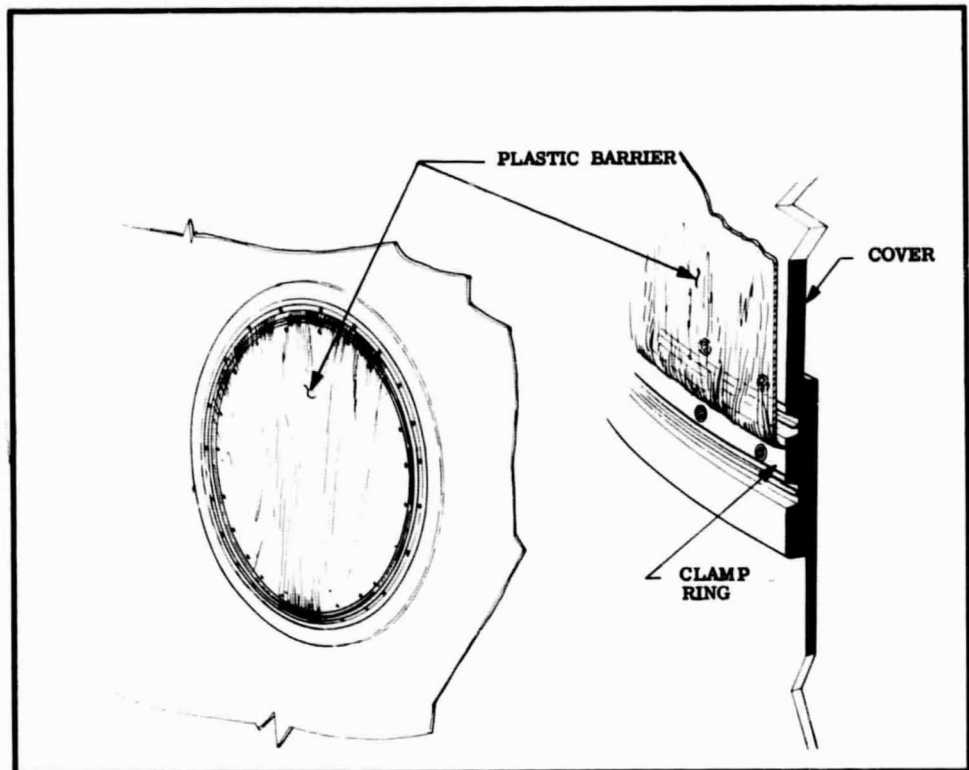


Fig. II-13 Design Concept 4

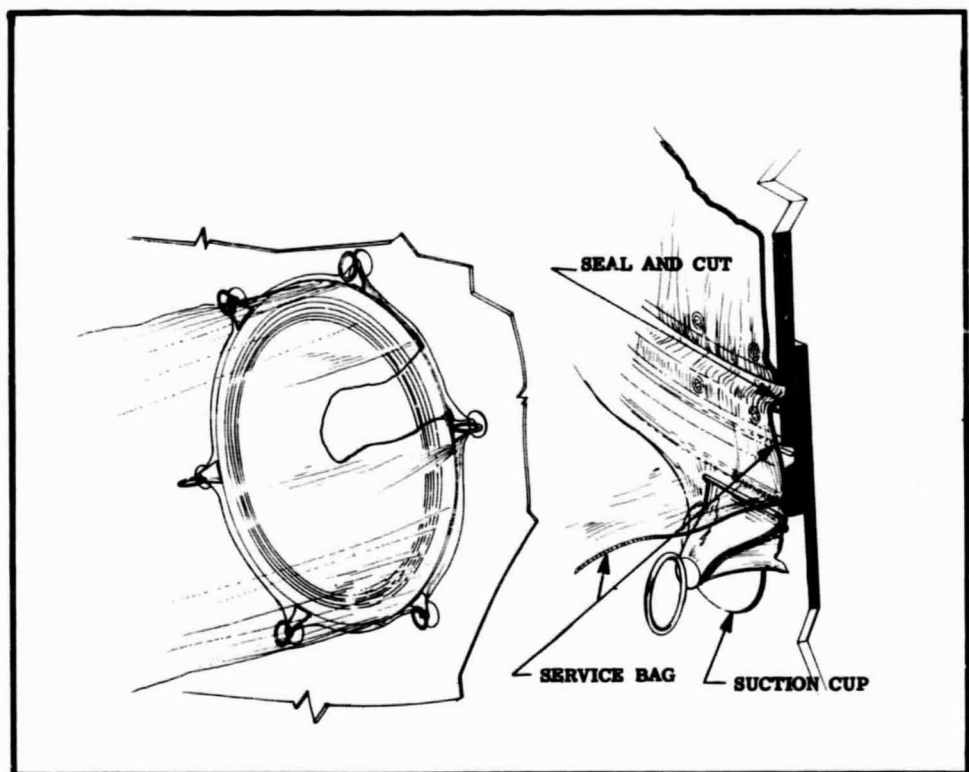


Fig. II-14 Design Concept 4, Service Bag Installation

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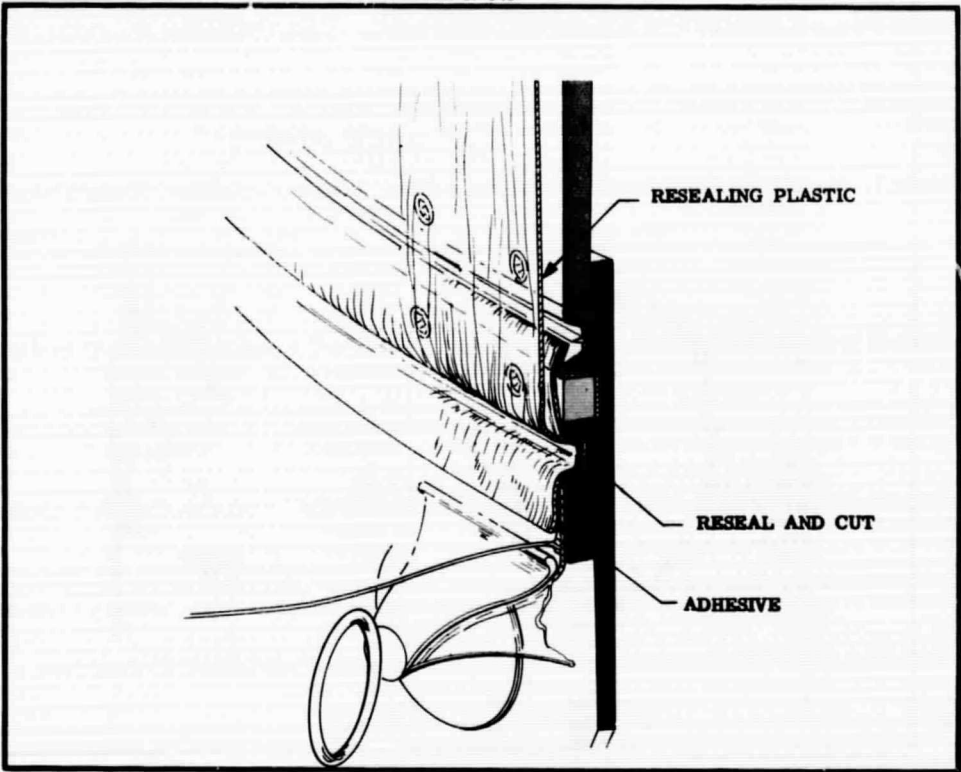


Fig. II-15 Design Concept 4, Removal of Center Disc

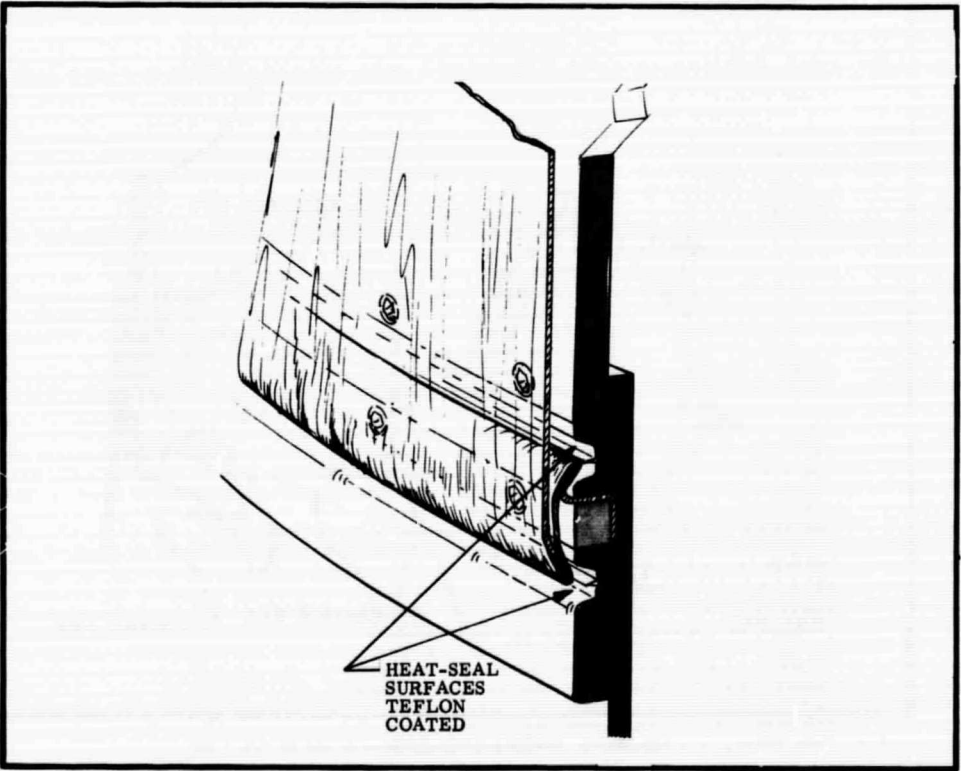


Fig. II-16 Design Concept 4, Removal of Service Bag

5. Heat-Sealing Tool 1 - Wheel Type

This heat-sealing tool (Fig. II-17 and II-18) can be used with all of the design concepts. The tool is operated by pressing and rolling it by hand on the heat-sealing surface. The wheel revolves on ball bearings. A press-on cover made from heat-insulating material is provided for protection against accidental heat damage to the service bag walls. A "normally-off" switch will be provided in the handle of the tool. Alternating current for the heating element is supplied through spring-loaded carbon brushes sliding on copper ring conductors. The third ring is used to carry the electric impulse from the temperature-sensor thermistor to a temperature-controlled switch outside the handle. Felt seals protect the interior of the wheel. The wheel can be used for all four design concepts by changing the rim configuration to suit the particular design of the heat-sealing surface. The depth of the groove in the wheel rim for Design Concept 1, in combination with the height of the raised heat-sealing surface at the entry port, offers some positive control of the amount of compression of the two plastic films. This design can be adapted to a battery power supply.

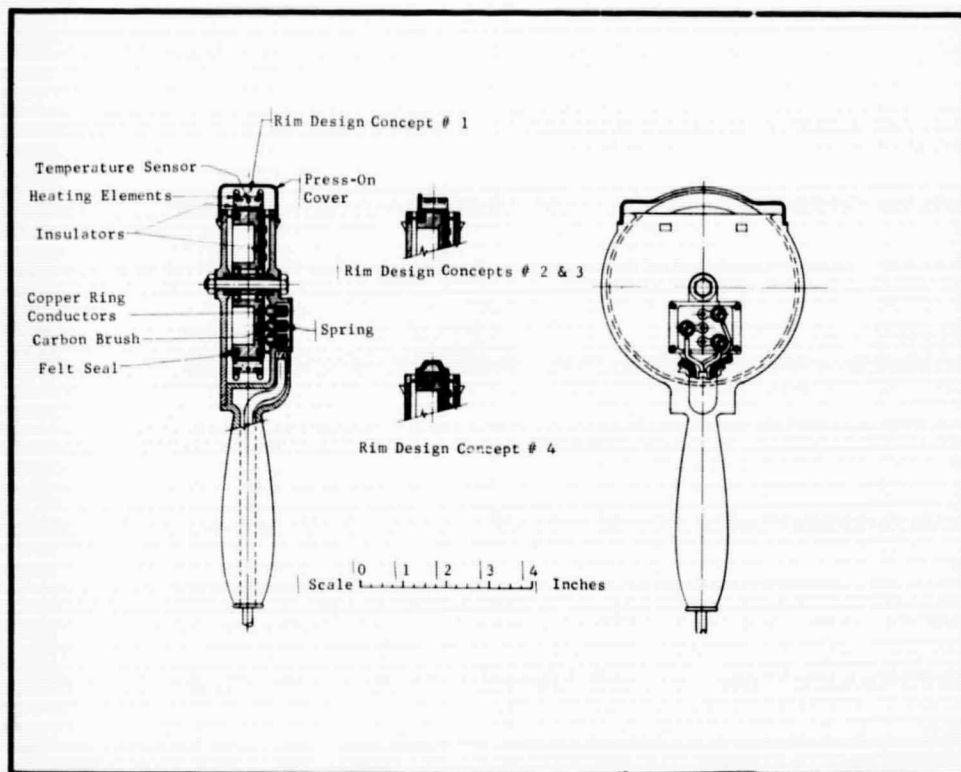


Fig. II-17 Wheel-Type Heat-Sealing Tool 1

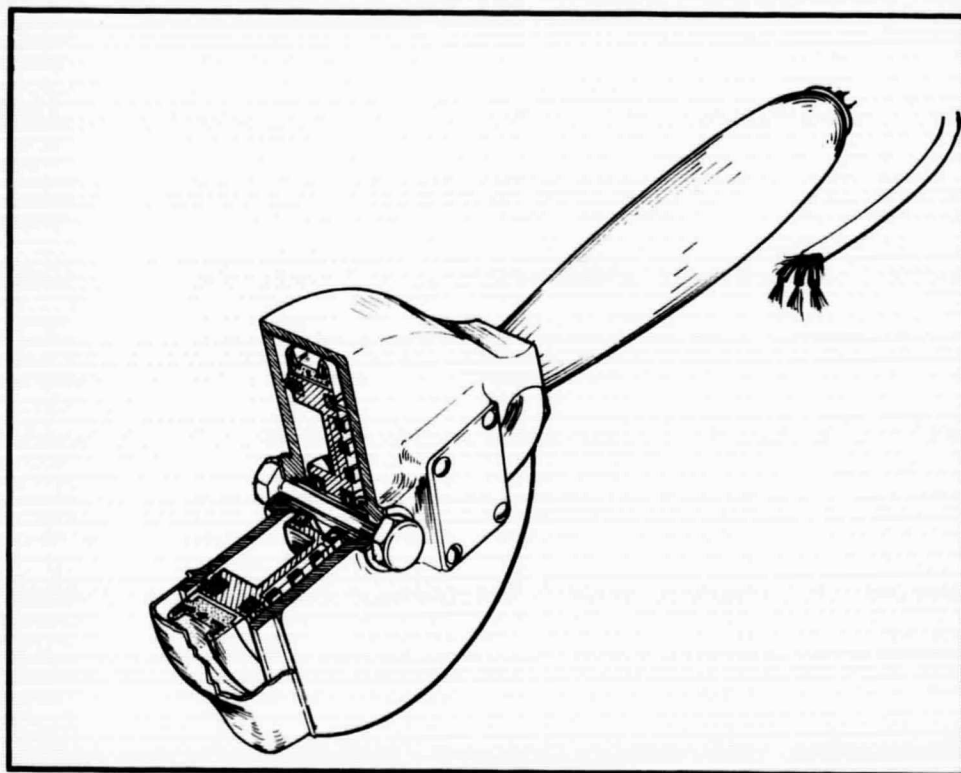


Fig. II-18 Cutaway of Wheel-Type Heat-Sealing Tool 1

6. Heat-Sealing Tool 2 - Single Ring

Figure II-19 shows a single-ring heat-sealing tool. The concept is based on the small ring-type tool fabricated by Martin Marietta under an earlier corporation-funded investigation of sterile insertion. Modifications have been made to provide a more uniform load distribution, which was considered to be a weakness in the earlier design. The heating element shown in Fig. II-19 is embedded in flexible material with a medium-hard silicone backing base. Both are mounted by anchor studs to the metal ring. A continuous tubular ring handle is provided for the operator. With this design, the maximum unit pressure in psi at the heat-sealing surface is limited by the load that the operator can manually apply at the tool handle.

Although suitable for use with any of the four design concepts, this approach requires two separate ring tools -- one for the initial sealing and a second for the resealing operation.

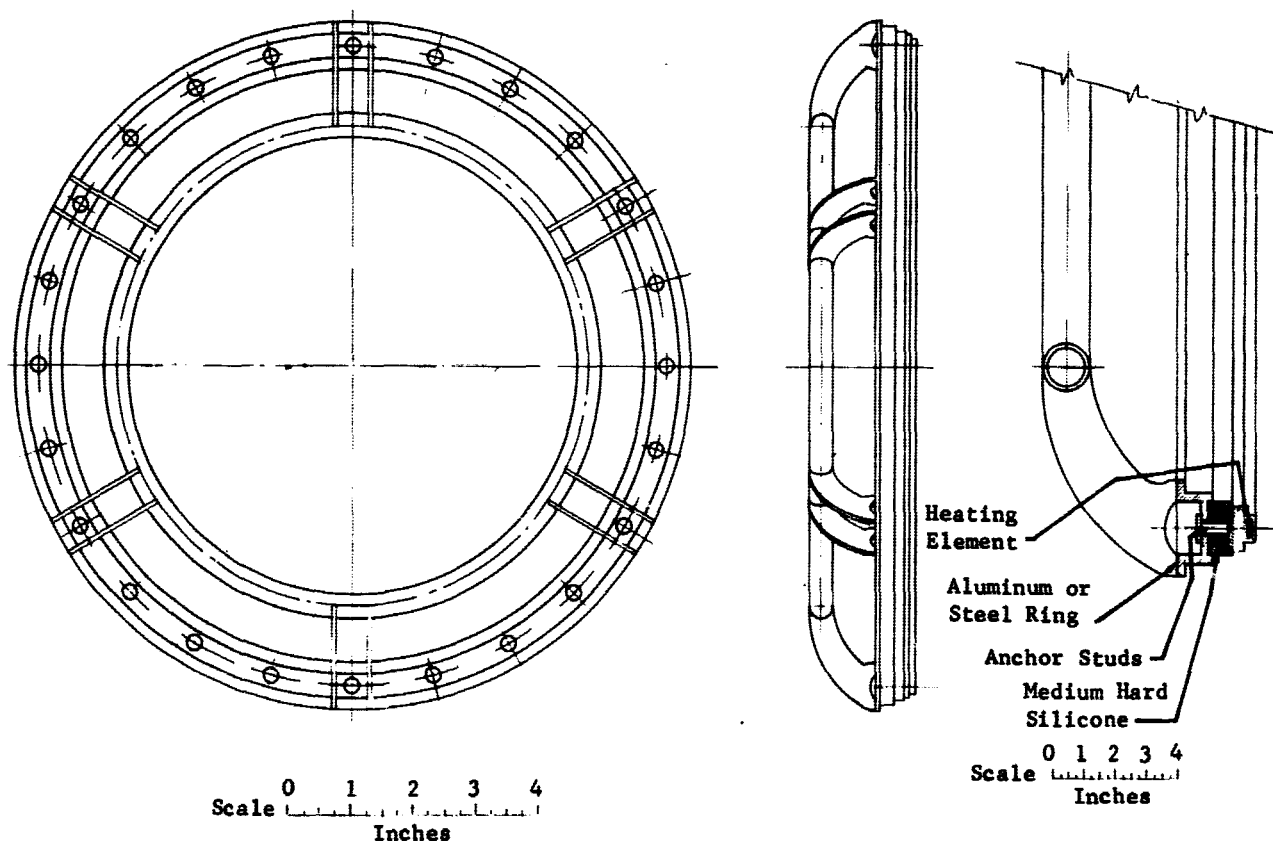


Fig. II-19 Single-Ring Heat-Sealing Tool 2

7. Cutting Tool 1 - Hot-Wire Type

Figure II-20 shows the design changes required to convert the roll on wheel-type heat sealing tool (Fig. II-17) to a hot-wire cutting tool. The main difference is in the design of the rim. The rim is cooled by insulating material, with the hot cutting blade protruding through it. Only two sets of carbon brushes and conductor rings are shown because no temperature control is anticipated. The drawing also shows the rim design when the tool is intended for use with Design Concepts 2 and 3. All other details are identical with the wheel-type heat-sealing tool.

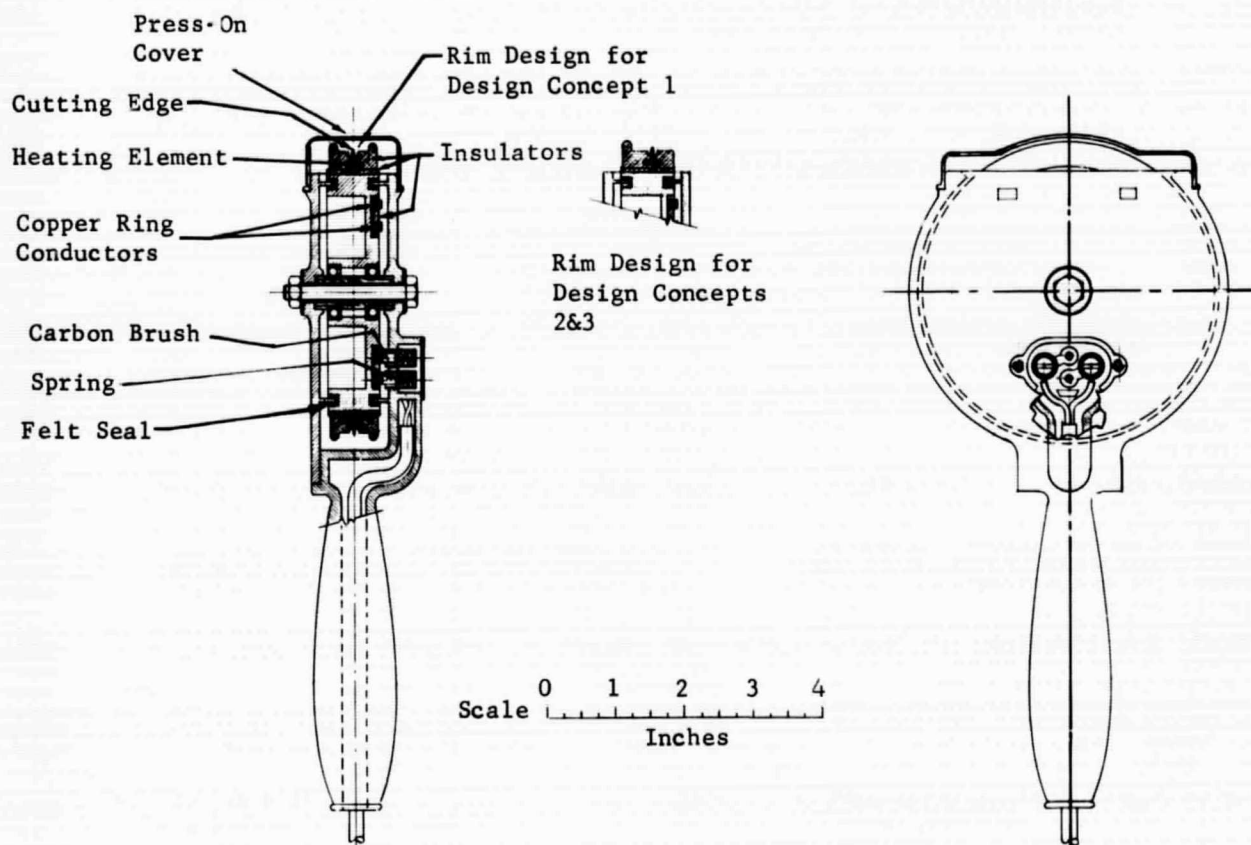


Fig. II-20 Hot-Wire Cutting Tool 1

8. Cutting Tool 2 - Power Blade

The conceptual design of this tool is shown in Fig. II-21 and II-22. The tool uses a power blade driven by a high-speed, miniature, fractional-horsepower AC electric motor. The two teflon-lined guide rollers control the penetration depth of the blade through the seam into inserts at the sealing surfaces.

The tool can be used with Design Concepts 1, 2 and 3 by using the corresponding guide-wheel design. The guide rollers run on teflon bearings; the electric motor shaft on ball bearings. A "normally off" switch is provided in the handle.

9. Cutting Tool 3 - Rolling-Blade

Figure II-23 shows the simple rolling-blade cutting tool. A circular cutting blade is mounted on a roller. A second wheel that fits over the heat-sealing surfaces serves as a guide. The guide wheel can be designed to match Design Concepts 1, 2 or 3. The tool handle is provided with a position selector that can place the handle at any angle from 15° to 75° to the cutting surface.

10. Preliminary Design Concepts - Evaluation

a. Port closures

If the external plastic barrier is broken, biological contamination does not enter the spacecraft because of the added protection afforded by the port cover behind the barrier. This condition permits remedial measures to be taken when breach of biological security occurs. However, the external barrier is more prone to breaking because of its exposure to external environments and handling.

Damage to the internal plastic barrier is much less likely to occur because of the protection afforded by the outer port cover. If this barrier is breached when the cover is removed, contamination of the spacecraft would occur and require a repetition of the terminal heat cycle.

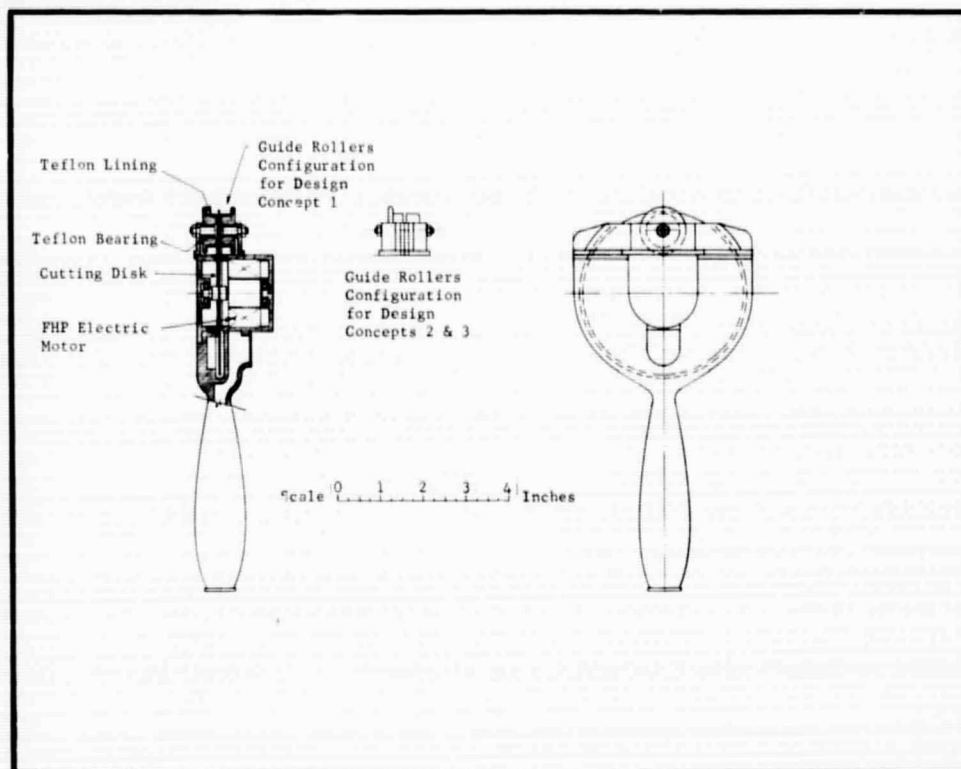


Fig. II-21 Power-Blade Cutting Tool 2

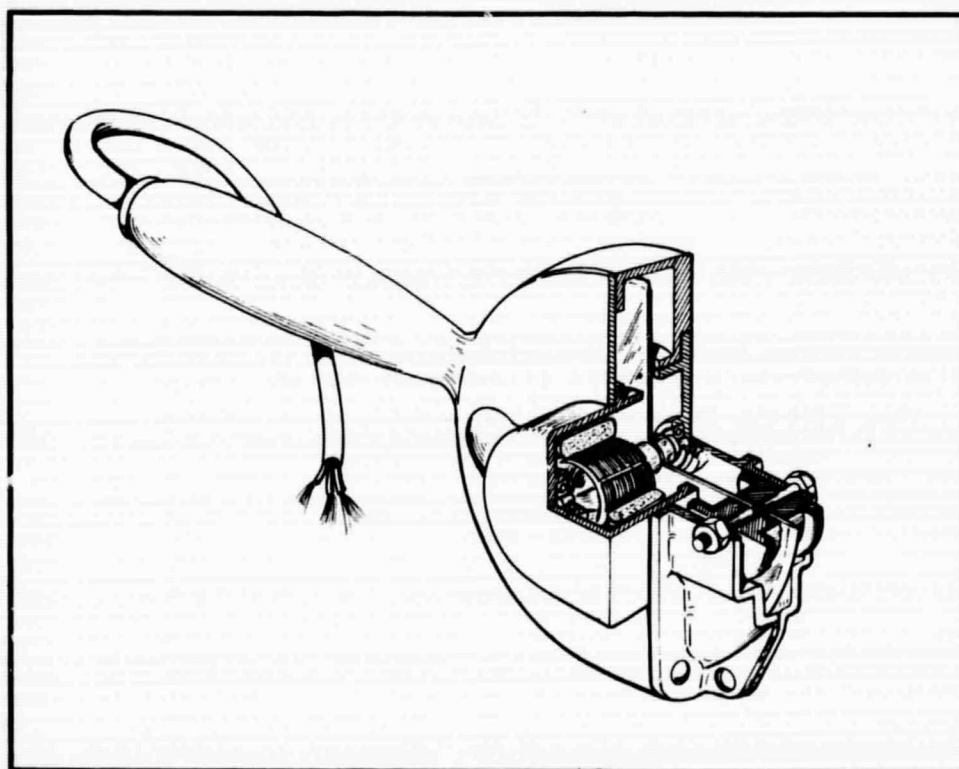


Fig. II-22 Cutaway of Power-Blade Cutting Tool 2

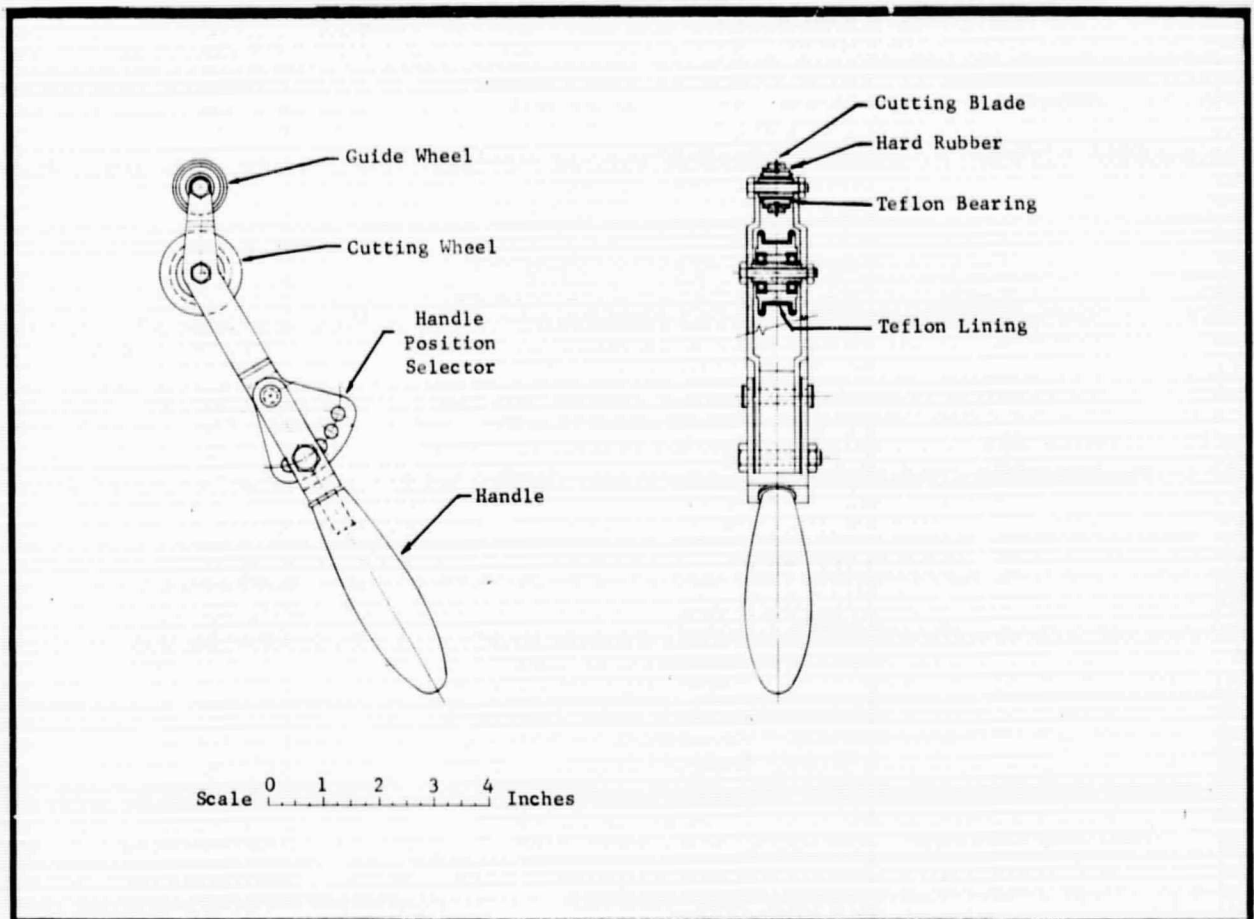


Fig. II-23 Roller-Blade Cutting Tool 3

b. Plastic Barrier Attachment

The clamp rings over the plastic-to-metal bonding points provide additional protection against accidental detachment of the plastic barrier.

c. Service-Bag Positioning

Spring-loaded mechanical mounting latches are more reliable than suction cups. However, a latch assembly is more expensive than a suction cup. The suction cups also offer a larger span of adjustment when compared to the limitations imposed on the mechanical latches by the mounting bracket. The mounting ring of the service bag for Design Concept 2 is very accurate and reliable

Table II-1 Design Concepts Summary

Design Areas	Design Approaches	Design Concept No.
1. Port closure	External plastic barrier with an internal port cover	1, 3 & 4
	Internal plastic barrier with an external protective cover	2
2. Plastic barrier attachment	Heat fusion to port opening frame*	--
	Heat bond & clamp ring	1, 2, 3 & 4
	Thermosetting adhesive*	--
3. Service Bag Positioning	Spring-loaded mounting latch	1
	Mounting ring with spline lock	2
	Elastic band with preformed service bag	3
	Suction cups	4
	Electromagnetic clamp*	--
	Tolerance fit with pressure*	--
	Manual support*	--
4. Heat sealing & cutting surfaces	Raised with guide edges	1, 2 & 3
	Grooved	4
	Teflon-type coating	1, 2, 3 & 4
	Cutting blade protection inserts	1, 2, 3 & 4
5. Heat sealing tools	Roller wheel	1, 2, 3 & 4
	Pressure ring	1, 2 & 4
	Integral heater strips*	--
6. Cutting tools	Hot-wire roll-on wheel	1, 2 & 3
	Power blade	1, 2 & 3
	Cold wire in groove	4
	Guided roller blade	1, 2 & 3
7. Resealing plastic positioning	Adhesive bond	1, 2 & 4
	Adhesive tape	1, 2 & 4
	Elastic band with preformed plastic film	3
*Evaluated & rejected.		

but is also very expensive. Scale-up for larger size service ports may become a problem due to the large diameter rings to be fabricated and the weight to be handled when installing the bag. Elastic bands in combination with a preformed service-bag base and resealing plastic films offer superior wrinkle-free positioning of the plastic films over the heat-sealing surfaces at relatively lower cost than the mounting-ring method.

d. Heat-Sealing and Cutting Surfaces

Two guide edges for the heat-sealing surfaces allow for some compression control during sealing. Grooved heat-sealing surfaces offer safe places for attachment of cutting wires.

e. Heat-Sealing Tools

Heat-sealing Tool 1 (wheel type) applies the heat over a very small area. Heat application time is left entirely to human judgment.

Scale-up potentials of the manual single-ring Heat-Sealing Tool 2 are limited.

f. Cutting Tools

Cutting Tool 3 (rolling-blade type) is simple and inexpensive. However, a power blade is required for hard-to-cut films. The hot-wire tool offers the safety of additional sterilization at the cutting line. Fixed cutting wires in the grooved heat-sealing surface eliminate the requirement for a portable cutting tool.

11. Summary

Table II-1 summarizes approaches considered of major importance to the design of the four preliminary concepts.

B. DESIGN REVIEW OF INITIAL CONCEPTS

1. Martin Marietta Design Review

Before the formal contractual design review with NASA personnel, a Martin Marietta internal design review was held. Review Board members included representatives from design engineering, manufacturing, quality, and the biology laboratory. In addition to detailed evaluation and critique of each design, the reviewers rated the concepts using a checklist covering reliability, safety, cost, ease of operation, ease of manufacturing, weight penalty, and time required for the operation. Their recommendations and evaluations were used by the Program Manager and his key personnel to improve the design concepts and to identify the major decision factors between the alternatives.

2. Contractual Design Review

A midterm design review was held at Goddard Space Flight Center in compliance with contractual obligations. The designs described in Section A were presented at this meeting. As an outgrowth of the discussion and constructive comments by personnel from NASA Headquarters, NASA-Langley Research Center, NASA-Marshall Space Flight Center, NASA-Goddard Space Flight Center and Designers and Engineers, Inc., the following basic decisions were made:

a. Design Semiautomatic or Fully Automatic Tools

Although the statement of work defined manually operated heat sealing and cutting tools, high reliability required for spacecraft application calls for tools that would be relatively independent of human strength, skills, judgment, and error. This fact led to NASA direction to reorient the designs to semiautomatic or fully automatic tools.

b. Design a Mobile and a Rigid, Ring-Type Heat-Sealing Tool

For large sterile insertion applications such as Voyager self-driven fully automatic tools were considered necessary. On the other hand, small probes could be sealed by a single application of a rigid ring-type tool. To encompass both of the projected needs, development of a design for each was directed, with primary emphasis on the more versatile mobile concept.

- c. Attach the Service Bag to the Spacecraft by Fastening Mechanisms on the Outside of the Bag

This design approach was considered more reliable than the alternatives.

- d. Use Internal Plastic Barriers

External plastic barriers offered an advantage of ease of detection of breaches of biological security, but suffered from exposure to external environments and handling that would foster such breaches. Internal barriers are protected from these external conditions and can yield high biological security by a double plastic bio-barrier, or by being sandwiched between two port covers with biological seals. Due to these positive features, NASA decided to limit further designs to the internal-barrier concept.

C. FINAL DESIGN CONCEPTS

As a direct result of discussions and decisions made at the midterm review, the two final design concepts differ considerably from the four presented at the midterm review. For spacecraft application, these later designs are considered best. However, all six design concepts are believed to be sound from an engineering standpoint. The earlier designs of heat-sealing and cutting tools may prove practical and valuable in other nonspace application, i.e., the pharmaceutical, medical, or packaging industry.

1. Design Concept A

This concept uses a self-propelled heat-sealing tool, a suitable entry-port design, and a self-propelled cutting tool. For uniformity of design with the preliminary design concepts, this concept is sized for an 18-inch diameter entry port. However, the corresponding heat-sealing tool can be adjusted to operate on any size port opening.

a. Heat-Sealing Tool

The self-propelled caterpillar-type heat sealing tool for Design Concept A (Fig. II-24) is designed to travel on a rail around the entry port. The tool is intended to provide the operator with accurate and automatic control of pressure, temperature, and heat application time for the heat-sealing seam. The traveling rail is rectangular in cross section and the tool grips it on both sides at the heat-sealing surfaces. The flat, slightly recessed sides of the rail guide the tool on the rail and prevent it from falling off. The cutaway view of the tool shows, among other details, the belt drive shaft and bearings assembly (Fig. II-24).

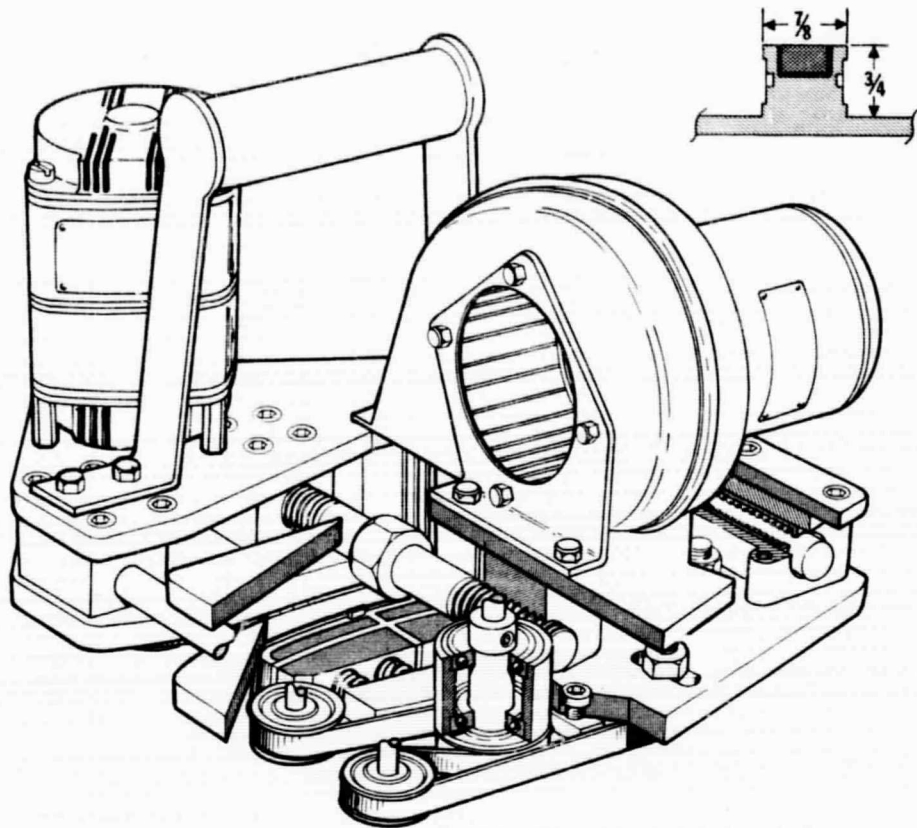


Fig. II-24 Design Concept A, Heat-Sealing Tool

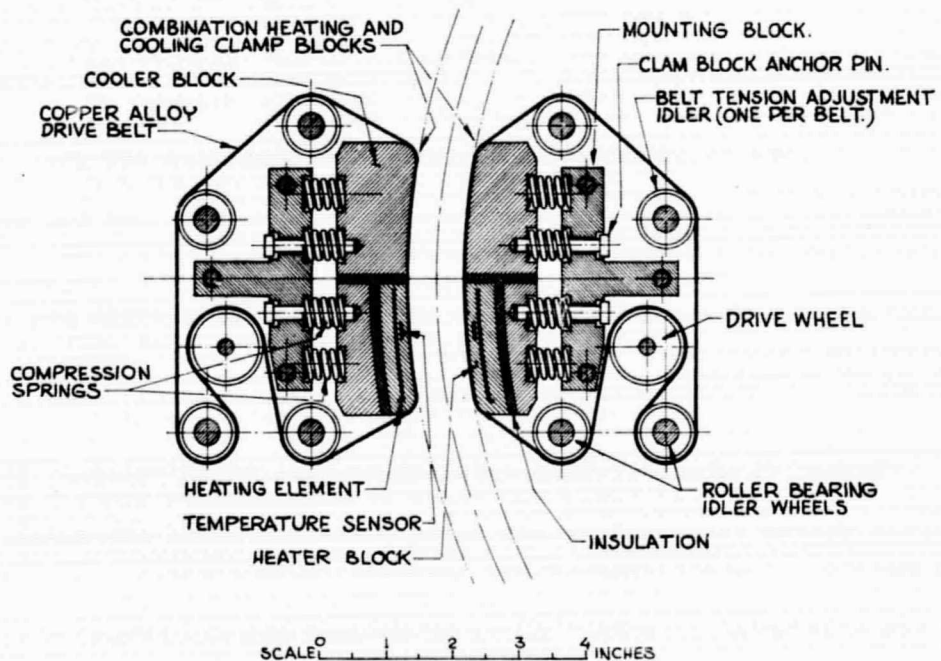


Fig. II-25 Section through Base of Heat-Sealing Tool, Design Concept A

A section through the base of the tool (Fig. II-25) shows the clamp blocks that contain the heating blocks, with their heating elements and temperature control thermistor sensors and the cooling blocks. The heating elements are energized separately so that sealing can never be done simultaneously on both sides of the rail. Each clamp block is attached through springs to the mounting block. The two sets of springs are supplied with a deflection meter indicator that interprets spring deflection to clamp surface load in psi. The self-propelled caterpillar movement is obtained by two power-driven copper-alloy endless belts that ride on several roller bearing idlers. The belts are ML Kapton coated to prevent the belt from sticking to the plastic. One idler on each belt is adjustable for belt tensioning. This adjustment is made after the tool is clamped to the rail and the correct sealing pressure obtained. A teflon-type coating is applied to the clamp block surfaces for lower belt friction. The idlers and drive wheels are lined with medium-hard neoprene or silicone. The ratio between the diameters of the two drive wheels is determined by the length ratio of the circumferences traveled by the two belts. The anchor pins hold the clamps to the mounting blocks.

The cooling blocks have fins that extend through the openings in the basic mounting plates as shown in Fig. II-26. The two guide rods that ride on ball bushings, and the clamp screw, hold the two clamp block assemblies of the tool together. The mounting slots for the belt tensioning idlers, the location of the drive shafts, couplings, and bearings are also shown. The screw blocks and the bearing blocks for the guide rods serve as spacers between the basic plates and the power system mounting plates.

Figure II-27 is a plan view of the tool with the two geared fractional horsepower drive motors, cooling blower, and lifting handle in position. The motors are synchronized and the anticipated output speed of the drive shaft will be between 2 and 10 rpm at 100 in-oz approximate minimum torque. A variable-speed motor-control unit serving both motors will provide the required variation in motor rpm, thus providing the tool with an ample range of travel-time control.*

*Travel time and sealing temperature will be established from biological kill data being developed in NASA-Goddard studies and Martin Marietta investigations being performed under the auspices of Marshall Space Flight Center (Contract NAS8-21122).

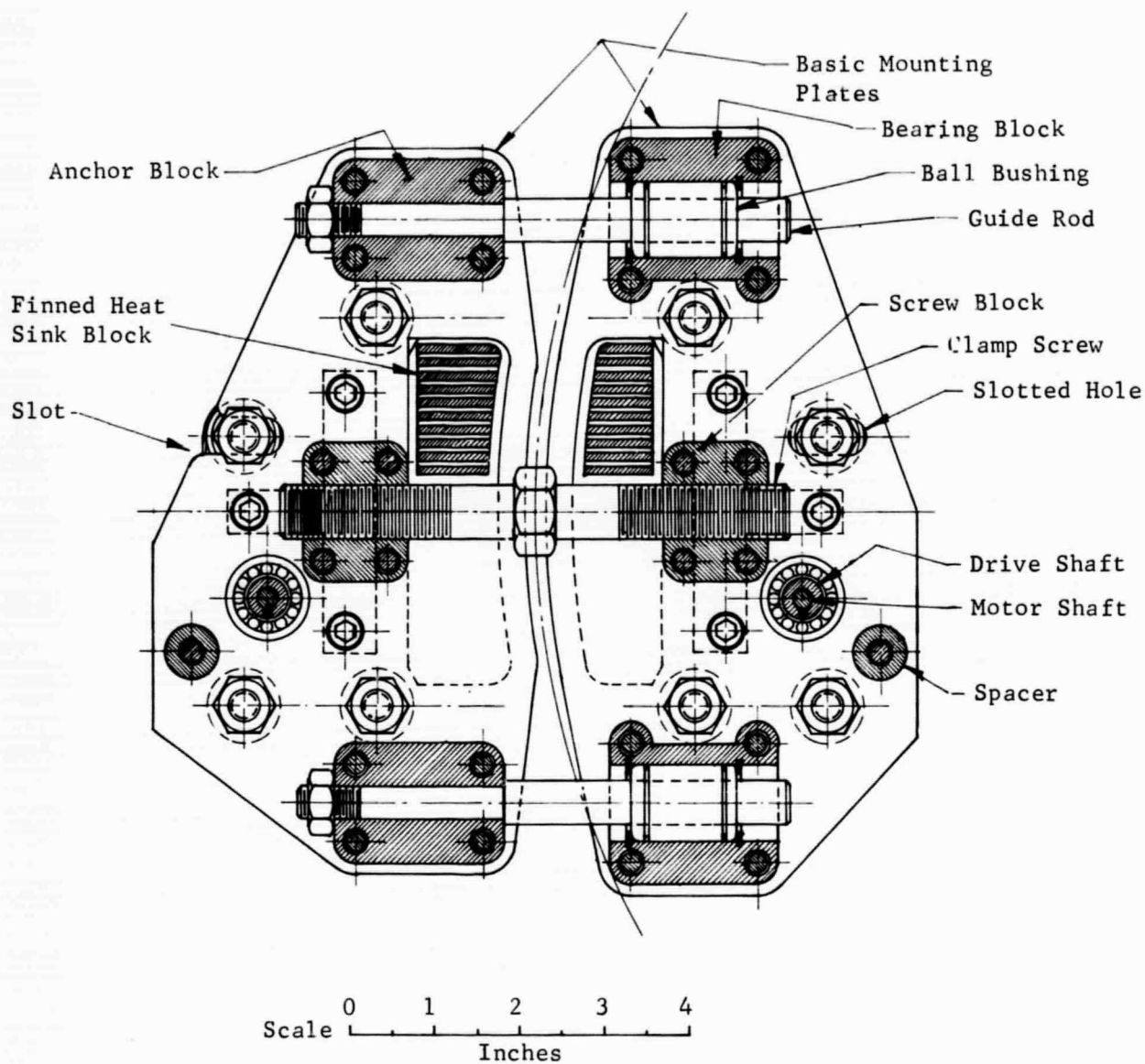


Fig. II-26 Design Concept A, Heat-Sealing Tool with Fins through Mounting Plates

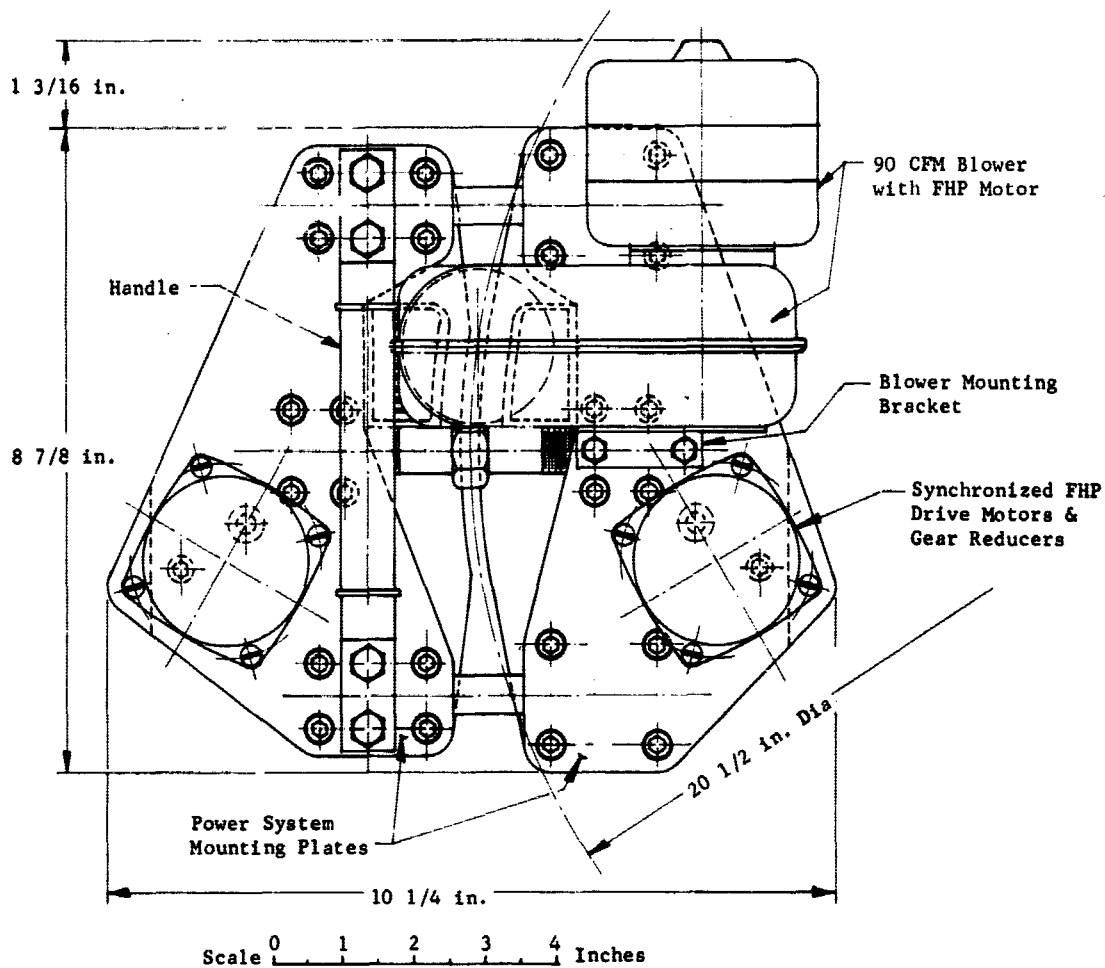


Fig. II-27 Plan View of Design Concept A, Heat-Sealing Tool

The fractional horsepower motor driven blower recirculates cooling air through the cooling block fins at the rate of 50 to 90 cfm, ensuring a fast temperature drop in the hot seam when the cooling block passes over it. The complete heat sealing tool assembly will weigh between 12 and 15 lb.

b. Entry-Port and Service-Bag Design

Design Concept A requires preformed plastic films for the primary barrier, the service bag base, and the resealing plastic. The pitch circle of the heat-sealing tool rail should be approximately 2-1/2 inches larger in diameter than the port opening.

The primary plastic barrier (Fig. II-28) is bonded and clamped into the recess at the top of the rail by a clamp ring. The heat sealing surfaces have teflon-type coating and are provided with asbestos or hard silicon inserts to protect the cutting tool blade.

The outer cover fits over the rail and seals the primary barrier against contamination. It is, therefore, anticipated that when sterile insertion is required, the amount of biological contamination buildup on the outer surface of the primary barrier would be directly related to the time between the removal of the outer cover and the attachment and heat sealing of the service bag to the barrier.

The inner cover acts as the second biological barrier and is directly behind the primary barrier.

The service bag (Fig. II-29) is provided with a solid mounting base that is attached to the spacecraft wall by six or more elastic band assemblies. The alignment blocks allow accurate positioning of the mounting base over the port. The base diameter should be 13-5/8 inches larger than the pitch-circle diameter of the rail to allow freedom of movement for the heat-sealing tool inside the service bag. Heat sealing of the service bag to the plastic barrier is done on the inner heat-sealing surface of the rail.

The center disc, consisting of double plastic film sealed at the periphery with the contaminated surfaces trapped inside, is removed (Fig. II-30) with the help of the cutting tool described in the following paragraph. The exposed inner cover is removed. After completion of the required service the cover is replaced in position. The sterilized preformed resealing plastic is mounted in position over the rail and the edges are fastened to the service bag by adhesive tape. The heat-sealing tool is again installed in position and energized and the resealing plastic is sealed to the service bag at the outer surface of the rail. The cutting tool is then used to cut away the service bag. The service-bag mounting base is detached and the outer cover is replaced to complete restoration of the entry port.

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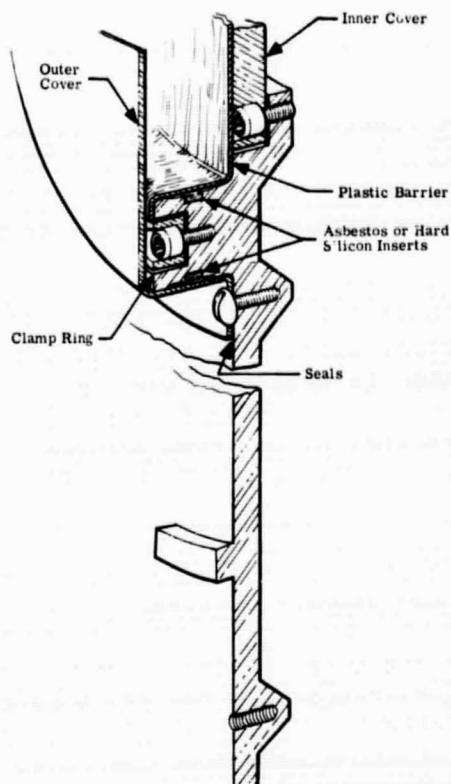


Fig. II-28 Design Concept A, Entry-Port and Service-Bag Design

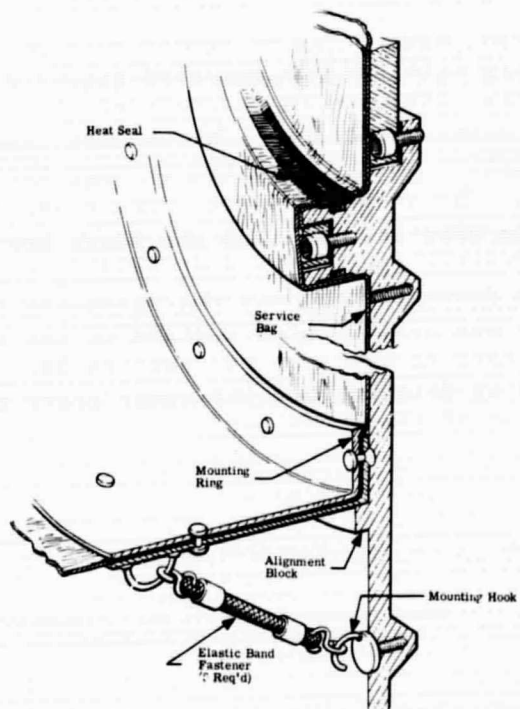


Fig. II-29 Design Concept A, Mounting of Service Bag

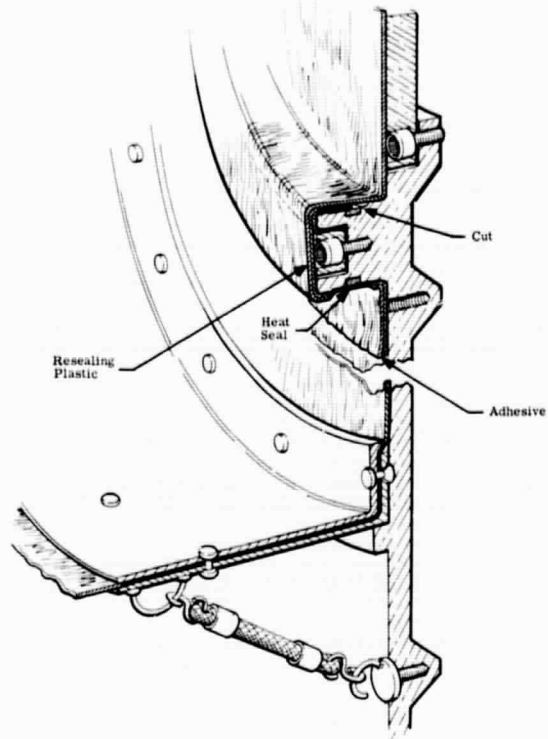


Fig. II-30 Design Concept A, Detail of Seal

c. Cutting Tool

The self-propelled cutting tool is shown in Fig. II-31. This tool is designed to travel on a rail the same way as the heat-sealing tool. It consists of four triangular hinge brackets joined at four hinge joints. Each hinge bracket carries a clamp wheel. All four wheels ride on the rail. Two of the wheels are plain roller bearing idlers. One wheel has the cutting blade and cuts through the seam as it rolls. The fourth wheel is the driving wheel and is mounted directly on the output shaft of a geared fractional horsepower motor. All four wheels are lined with medium soft neoprene. Two compression springs provide the clamping pressure required to hold the tool on the rail. The edge of the cutting blade is buried in the neoprene lining of the wheel and can cut only when the wheel is pressed against the side of the rail. Two handles at the center hinge joints are used to squeeze the tool open with one hand. A lock latch is provided to lock the tool in the open position when desired. The tool can operate on any rail curvature and on either side of the rail by turning it with the cutting wheel on the desired side. An engineering layout drawing (Fig. II-32) shows the overall size of the tool.

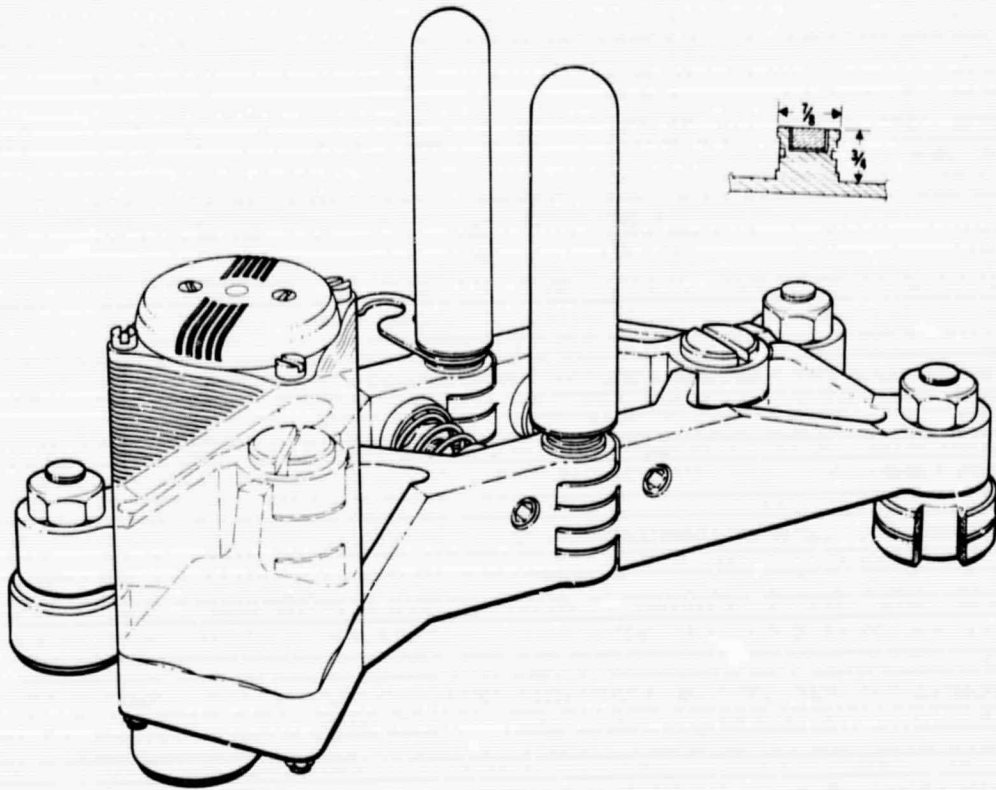


Fig. II-31 Design Concept A, Self-Propelled Cutting Tool

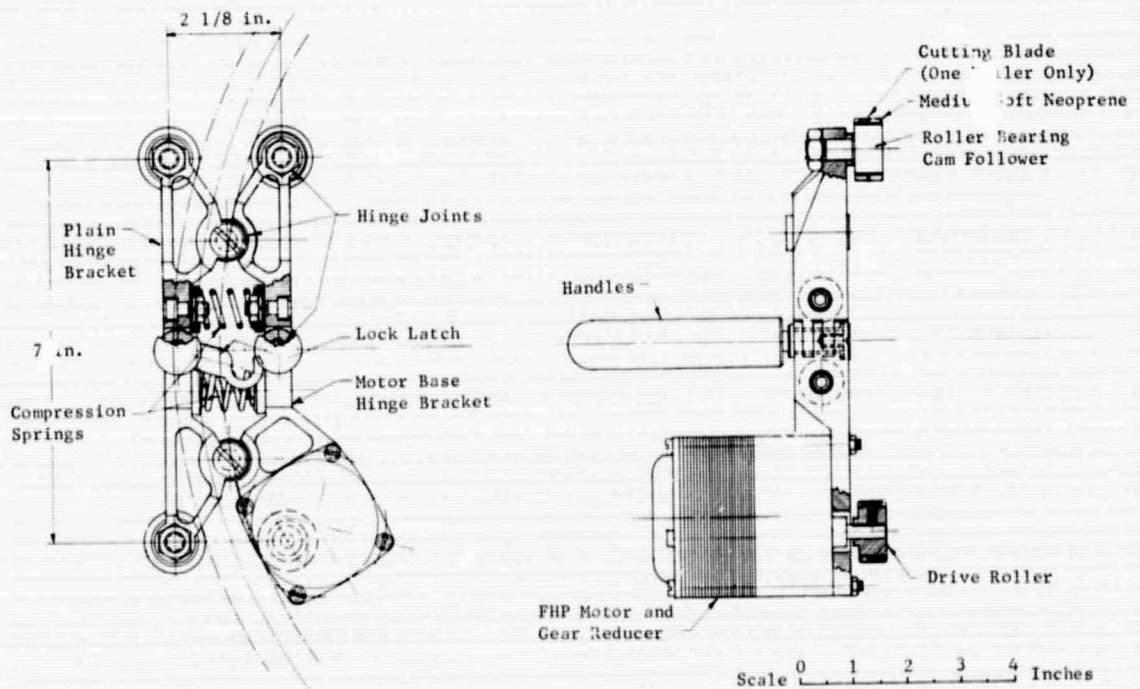


Fig. II-32 Design Concept A, Self-Propelled Cutting Tool Engineering Layout

2. Design Concept B

This concept uses a double-ring-type heat-sealing tool, a suitable entry-port design, the service bag, and a ring-type cutting tool.

For design uniformity, this concept, like all the other concepts, is sized for an 18-inch diameter entry port. The maximum practical size port that this tool can be designed for may not be much larger than the 18-inch diameter because the increased size and weight of heat-sealing and cutting tools will make them too difficult to handle.

a. Heat-Sealing Tool

The ring-type heat-sealing tool (Fig. II-33) consists of two concentric heater rings, one for initial heat sealing operations, and one for the resealing operation. The heating element of each ring is embedded in semiflexible material on a medium hard neoprene or silicone base. The two rings are mounted by anchor studs to a stiff metal ring base that is provided with two handles for manual installation. The heating ring flexibility is expected to improve load distribution over the seam. Each heat-sealing ring is provided with temperature control sensors.

b. Cutting Tool

The ring-type cutting tool (Fig. II-34) is designed to match the seams produced by the heat-sealing tool. The tool consists of two concentric rings of medium soft neoprene. A cutting blade, buried in the neoprene, is provided only for the inner ring because the tool is designed to cut through the seam between the primary plastic barrier and the service bag. The outer ring provides only a balanced load support. The second cut after resealing, to remove the service bag, is done by conventional means (scissors or knife).

c. Entry Port and Service Bag Design

Design Concept B does not require preformed plastic films. The primary plastic barrier (Fig. II-35) is bonded and clamped by a clamp ring around the opening. The inner cover is behind the primary barrier and acts as a secondary biological barrier. The heat-sealing surfaces are flush with the outer wall of the spacecraft and are coated with a teflon-type material. Asbestos or hard silicone inserts provide cutting-blade protection. The outer cover fits over the two heat-sealing surfaces and seals the primary barrier against biological contamination.

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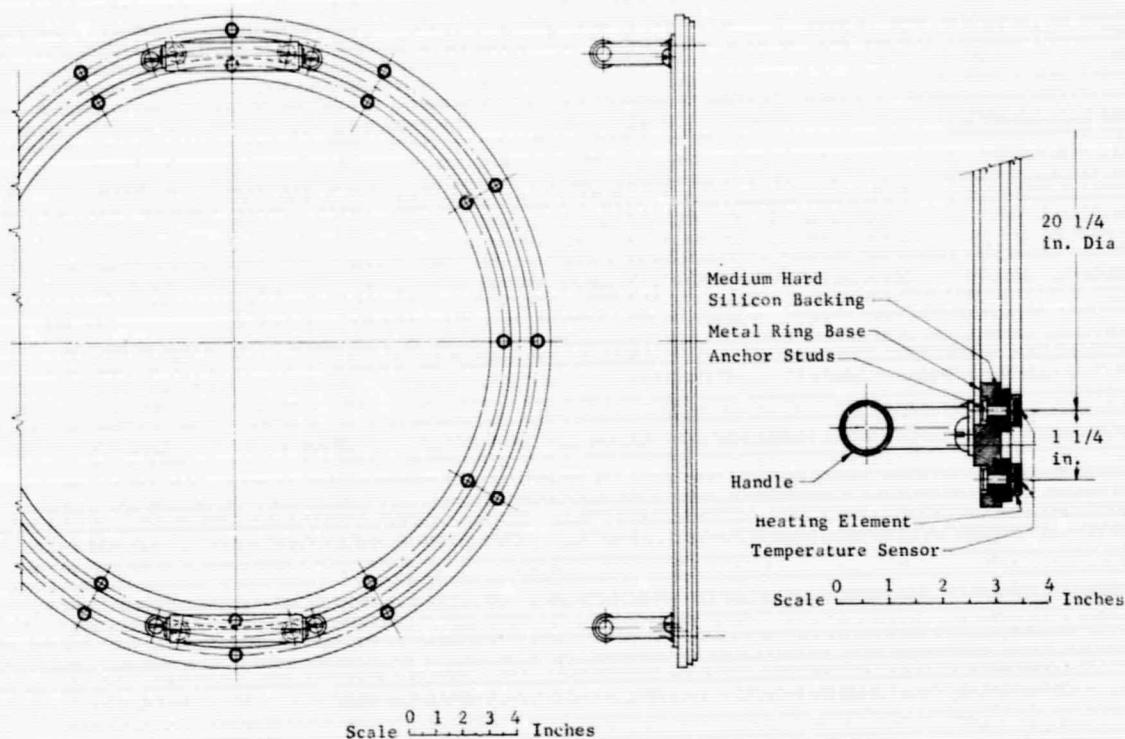


Fig. II-33 Design Concept B, Ring-Type Heat-Sealing Tool

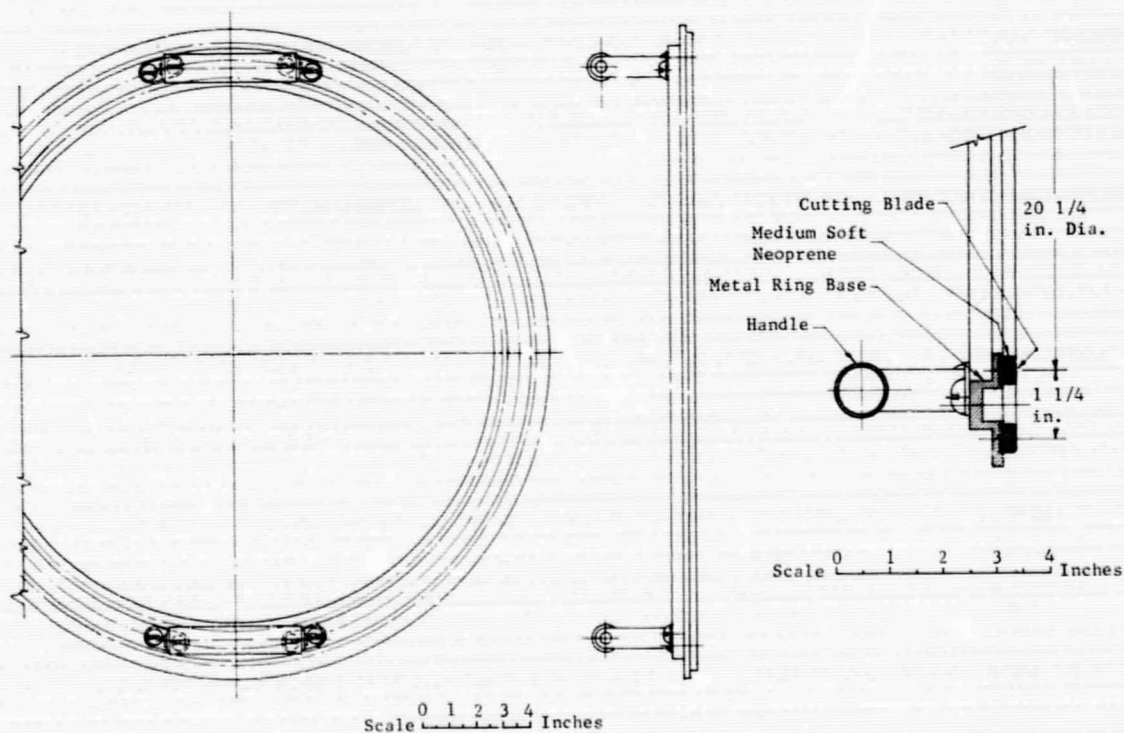


Fig. II-34 Design Concept B, Ring-Type Cutting Tool

The service bag (Fig. II-36) is provided with a solid mounting base ring that is bolted to the frame around the opening on the spacecraft. Fastened to the ring inside the bag are the mounting clamps for the heat-sealing or cutting tools. The clamps are spaced 10 to 12 inches apart (six clamps for this size design) and are designed to exert a maximum load of 500 pounds each on the tools. Load is adjusted by a crew. Strain gages incorporated in each clamp will give an accurate reading of the total load applied for heat sealing or cutting. The inner rim of the service bag mounting ring serves as the positioning register for the heat-sealing and cutting tools. The inner ring of the heat-sealing tool is energized to heat seal the service bag to the primary plastic barrier. After sealing, the heating tool is removed and replaced by the cutting tool. The center disc of the film is cut out and removed (Fig. II-37). The exposed inner cover is removed. After completion of the required service, the cover is replaced in position. The sterilized resealing circular plastic sheet is pasted in position over the opening (Fig. II-38). The heat-sealing tool is again clamped in position and the outer heating ring is energized, bonding the resealing plastic to the service bag. The service is cut away by conventional means. The service-bag mounting base ring is removed and the outer cover is replaced.

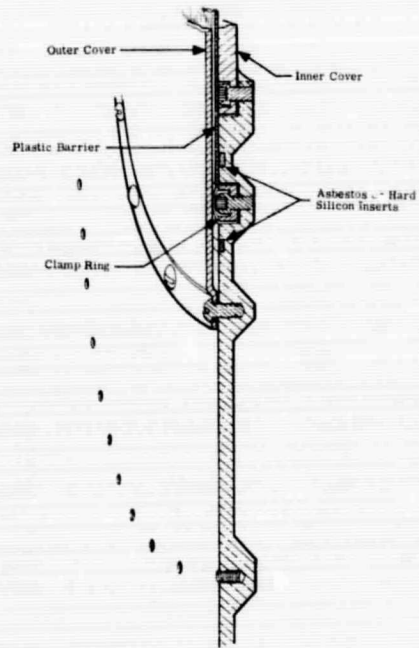


Fig. II-35 Design Concept B, Primary Plastic Barrier.

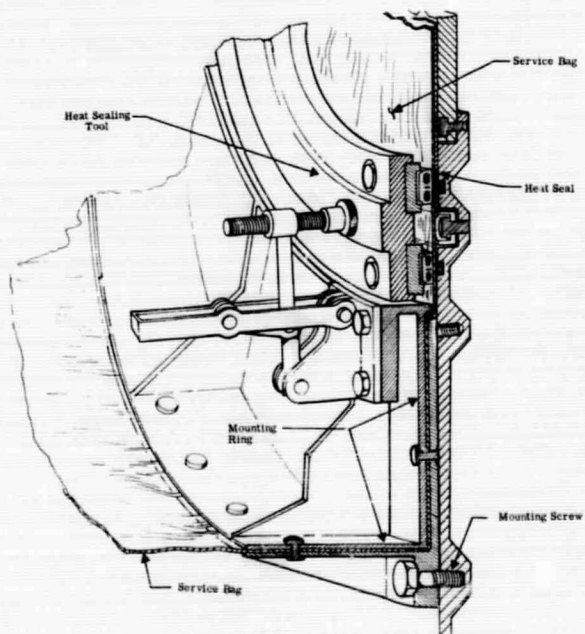


Fig. II-36 Design Concept B, Service Bag Installation

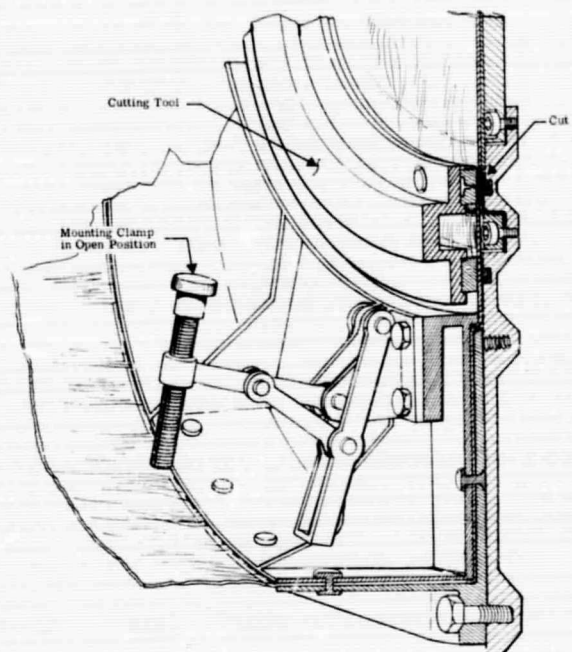


Fig. II-37 Design Concept B, Removal of Disc

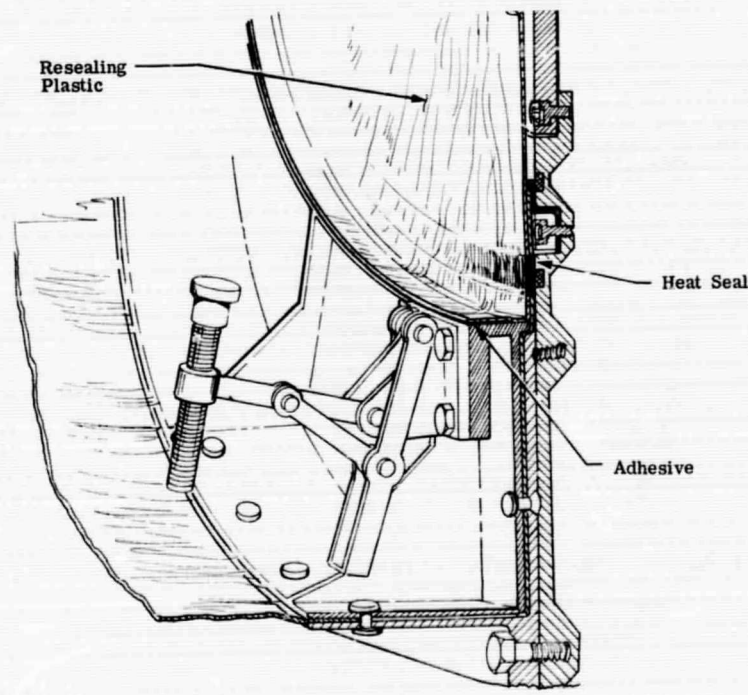


Fig. II-38 Design Concept B, Resealing

D. DESIGN REVIEWS OF FINAL CONCEPTS

1. Martin Marietta Design Reviews

A review board was convened to evaluate the final design concepts. The members were representatives of design engineering, manufacturing, quality control and the biology laboratory.

The two final design concepts were evaluated in detail, with particular attention to the self-propelled heat-sealing and cutting tools.

A proposed improvement of major importance was a simplification of the dual-caterpillar-type heat-sealing tool design to two single-caterpillar tools (Fig. II-39).

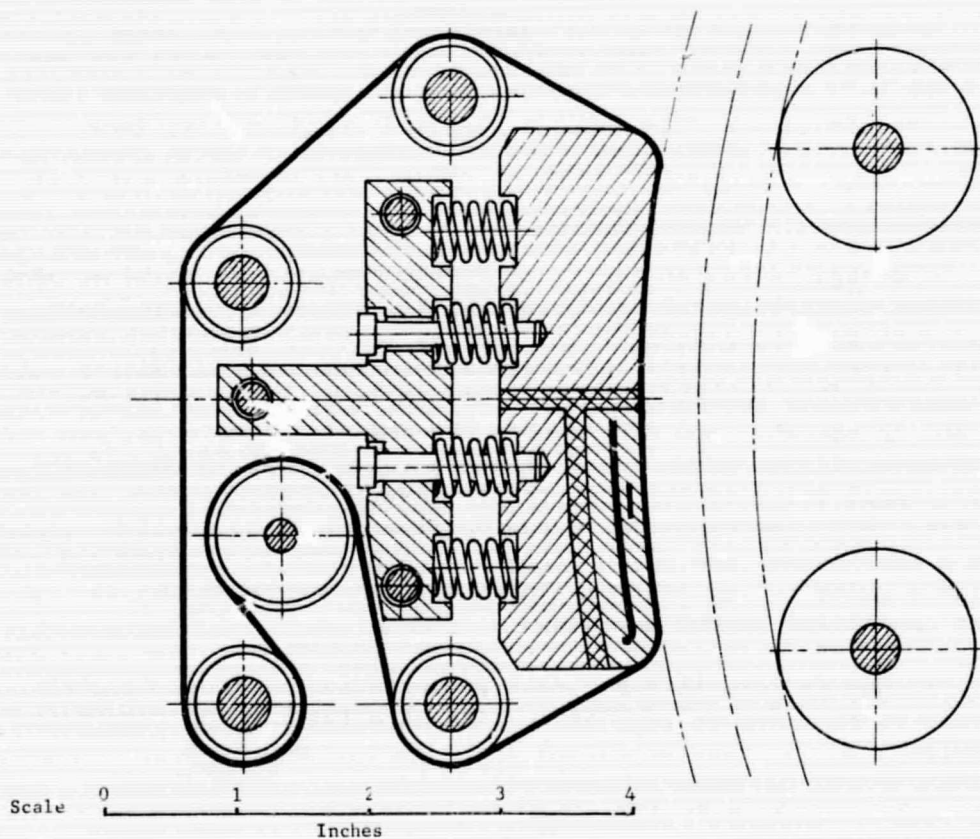


Fig. II-39 Simplified Design Concept A, Heat-Sealing Tool

The dual-caterpillar tool (Fig. II-24, II-25, II-26 and II-27) consists of two clamp-block assemblies each complete with drive system. The single caterpillar tool concept suggests the introduction of an unpowered guide-roller assembly. As an alternate to two separate tools, this assembly could be designed to operate separately with either of the two clamp block assemblies (Fig. II-39). The result will be two combinations of single caterpillar heat-sealing tools -- one for initial heat sealing on the inner surface of the rail, the other for resealing on the outer surface of the rail.

Although two tools are required, this design will eliminate the requirement for synchronized motors and the numerous problems connected with it.

The rollers also offer a better support for the tool on the guide rail, thus increasing the reliability of the tool. The weight of the new single caterpillar assembly will be less than the weight of the dual-caterpillar arrangement.

Some of the disadvantages are the time-consuming assembly and disassembly operations inside the service bag to obtain the required tool combination. The use of two entirely separate tools will eliminate assembly time at the expense of an additional blower and roller assembly.

2. Contractual Design Review

A design review of the final design concepts was held at NASA-Goddard Space Flight Center. It was recognized that the dual-caterpillar heat-sealing tool required more developmental effort than a tool incorporating a single caterpillar in combination with a guide-roller assembly. It was also felt that the additional steps to assemble and disassemble the heat-sealing tools from two caterpillars and one set of guide rollers was an undesirable additional activity for the sterile-insertion technician. On this basis, the major emphasis in the development phase would be placed on a tool incorporating the single caterpillar in combination with a guide roller assembly to be used in demonstrating the sealing capability on one surface.

It was decided that a formal presentation of these concepts would be made for other NASA centers at a forthcoming quarterly review.

III. MATERIALS EVALUATION

As a portion of this contract, the Martin Marietta Corporation has performed a materials evaluation in support of the design concept development effort. The purpose of this evaluation was to investigate various properties of heat-sealable plastic films for applicability to the sterile insertion concept. The materials evaluation effort was performed in two parts as planned in Martin Marietta Materials Engineering Test Plan ME 67/58P dated 29 May, 1967. Initially, a list of materials to be considered for this evaluation was prepared and investigated by a screening effort. Following a midterm contract review, the most promising materials were tested more extensively.

A. SCREENING TESTS

1. Discussion

The selection of candidate materials to be considered for this application was made from literature search and vendor or manufacturer discussions. The list that appears in Table III-1 includes materials with a wide range of heat-sealing temperatures, flexibility, and chemical properties. In general, the maximum-use temperature recommended by the vendors has governed the selection, although materials known to be marginal in temperature resistance were included to establish a basis of comparison.

The selection of a material for use in the sterile insertion concept presents a formidable problem because of the special environments required by the application.

Due to the effect on this application of the sterilization environments for planetary probes, screening tests were established that considered the effect of exposure to ethylene oxide/Freon 12 decontamination and thermal sterilization on physical properties of the films. Selection of materials to be recommended for further consideration was based on evaluation of the effects of the exposures described below on the tensile/peel strength of the films.

Table III-1 Candidate Materials

Material	Vendor Designation	Thickness (inch)
High-Density Polyethylene	Bakelite Hi-D/P.E.	0.004
Low-Density Polyethylene	Bakelite Low-D/P.E.	0.005
Polyvinylidene Fluoride	Kynar	0.001
	Kynar	0.002
Polycarbonate	Vendor Unknown	0.002
Polypropylene	Kordite S	0.006
Polycarbonate	Lexan	0.001
		0.005
		0.010
Polyvinylfluoride	Tedlar S	0.002
Nylon 6	Capran 77C	0.005
	Capran 77C	0.010
PTFCE	Aclar 22A	0.005
	Aclar 22C	0.005
	Aclar 33C	0.005
Polyester	Mylar 75	0.003
	M-22	
Polyimide Composite	Kapton HF	0.001/0.003/0.001
Fluorocarbon	FEP	0.002
	FEP	0.005
	FEP/TFE/FEP	0.005
Polysulfone	P.S. Film	0.005

a. Ethylene Oxide (ETO)/Freon 12 Decontamination

The sterilization criteria for unmanned planetary probes require a preliminary decontamination of the spacecraft hardware to reduce the bacterial load before initiation of the terminal sterilization procedure. This decontamination requires the exposure of the vehicle to an environment of ETO/Freon 12 (12/88 ratio) at $50\% \pm 5\%$ relative humidity and 35°C to 45°C for 30 hours (including time for chamber stabilization). Experience under NASA Contract NASw-1407 indicated that exposure to this environment caused degradation of plastic films used in that study. Therefore,

as a screening test, samples of candidate materials, both as a parent film and in the form of a heat-seal seamed interface, were subjected to the ETO/Freon 12 environment and then evaluated for signs of degradation.

b. Dry Heat Sterilization

Following ETO decontamination procedures, NASA requires terminal dry-heat sterilization of planetary landers. The procedure requires a 24-hour exposure at $125^{\circ}\text{C} \pm 2^{\circ}\text{C}$ in an N_2 atmosphere. The plastic materials used in this concept require resistance to this environment with no embrittlement, loss of physical properties, or effect on heat-sealing capability. The 125°C temperature, eliminates a wide spectrum of materials from consideration.

2. Test Procedures

a. Preparation of Screening Test Samples

The samples of the parent material for screening tests consisted of 1-inch-wide by 5-inch-long tensile samples of each material and thickness considered. A precision die, accurate to these dimensions within ± 0.003 inch, was made for cutting the material to test sample size. Surgical scalpels were used to cut along the edge of the die pressed firmly in place on the material. Samples requiring seaming before exposure to the screening environments were prepared by using a 3-inch by 6-inch (± 0.003 inch) die to cut material to size. A pair of these sheets was then overlaid and seamed one-half inch from the long edge using heat-sealing conditions approximately at the center of the vendor's recommended range of conditions. These seams were formed to produce a peel-type joint. The sealed sample was then cut into strips 1.0 ± 0.003 inch wide with three strips retained as controls and three subjected to the sterilization environments.

b. Sterilization Environments

- 1) ETO/Freon 12 - Exposure to a gaseous ETO/Freon 12 mixture was performed using the following step-by-step procedure:

Place test load in the chamber and seal chamber;

Start heat pump, controlling heat-transfer fluid temperature to $40^{\circ}\text{C} \pm 5^{\circ}\text{C}$;

Inject $50\% \pm 5\%$ relative humidity air until chamber relative humidity is stable at that level;

Close air valves and start vacuum system, pump to 70 ± 5 torr;

Back fill with ETO/Freon 12 gaseous atmosphere in a period of 30 ± 15 minutes, start gas recirculation pump;

Circulate decontamination gas through conditioning system until humidity of 35 to 45% is obtained;

Control ETO concentration pressure, temperature, and humidity until end of 24.5-hours decontamination cycle;

Vent chamber;

Perform vacuum cycle to 70 ± 5 torr;

Backfill chamber with air through the absolute bacteria retention filter;

Open chamber and remove samples.

- 2) Terminal Dry Heat - Exposure to the elevated temperature conditions of terminal sterilization was accomplished by the following procedure:

Place test load in the vacuum oven and seal the chamber;

Start purge of chamber at 2 psi with dry (99%) nitrogen, continue purge for 10 minutes, adjust chamber vent valve for steady flow rate;

Close vent valve and evacuate chamber to 70 ± 5 torr;

Backfill chamber with dry nitrogen and establish flow rate of 0.2 psi;

Turn on heat and bring oven to temperature of $125^\circ \pm 5^\circ\text{C}$ within one hour;

Maintain 0.2 psi N_2 purge and temperature of 125°C for 24.5 hours;

Turn down oven controller and set to return to ambient in approximately one hour, maintaining dry N_2 purge;

When sample reaches ambient temperature, close N_2 valve, open chamber, and remove sample.

c. Test

Following the environmental exposures, all samples including the control samples were tested as follows:

- 1) Visual inspection - The exposed samples were compared with controls for signs of distortion, shrinkage, curling, discoloration, melting, crazing, blistering (in seamed areas only), or other apparent degradation.
- 2) Physical test - Each sample of parent or seamed material was placed in the grips of a BLH tensile machine and tested in tension at a loading rate of 20 inches/minute. The ultimate strength of the material (or seam) was recorded and an approximation of the elongation before failure noted. Comparison of the data for exposed versus unexposed material was the basis for evaluation of the effects of the sterilization environments on the candidate materials.

d. Test Results

A summary of screening test results is presented in (Fig. III-1 and III-2) indicating the percent variation of the parent or virgin materials properties after exposure to the sterilization environments. A majority of the materials listed in Table III-1 showed significant degradation. However, six materials were found to exhibit little or no change in properties. The data for these tests are presented in the Appendix.

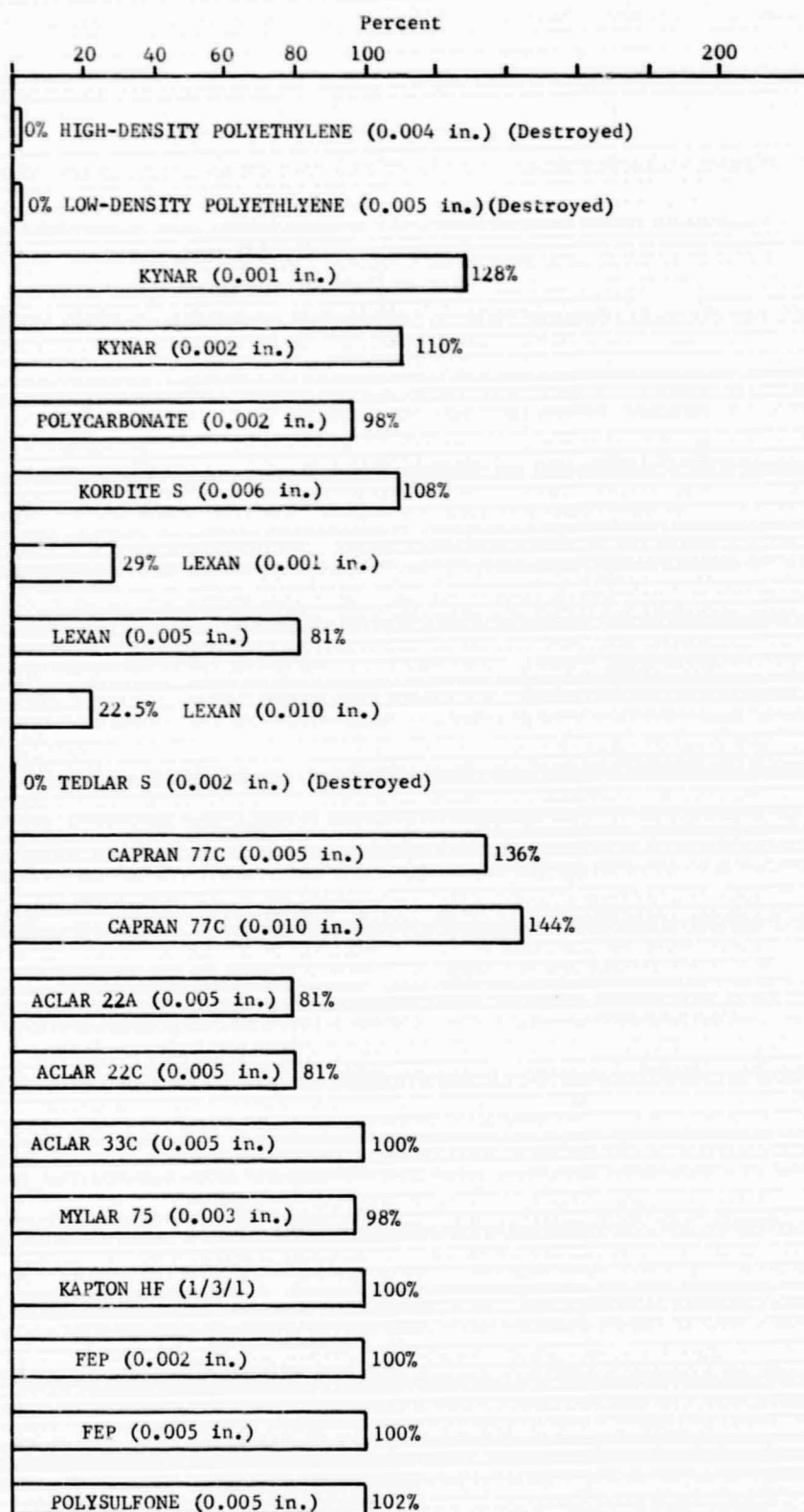


Fig. III-1 Percent of Original Tensile Strength After Sterilization

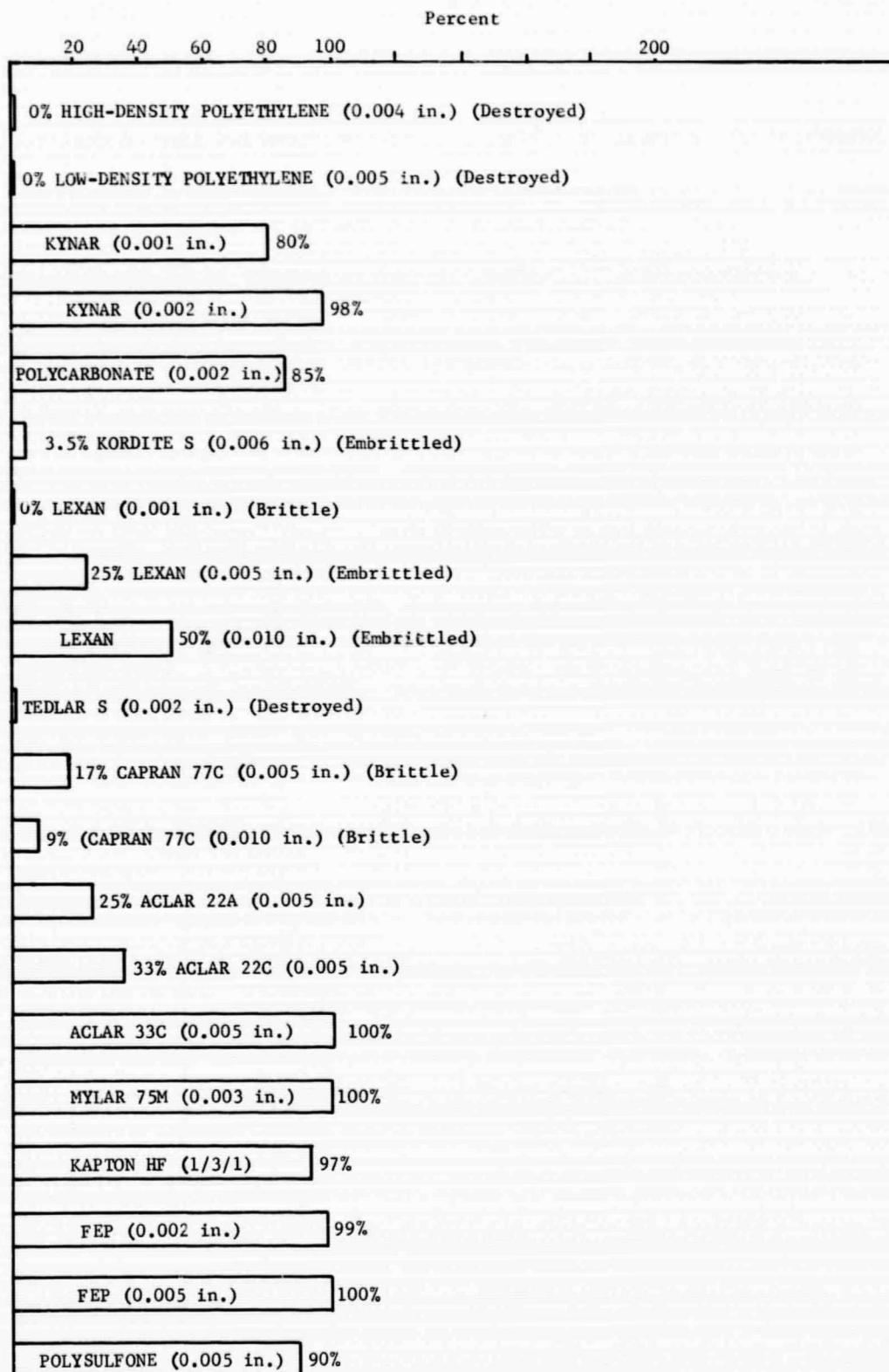


Fig. III-2 Percent of Elongation Retained After Sterilization (% of Virgin Elongation)

B. DESIGN REVIEW OF CANDIDATE MATERIALS

At the conclusion of the screening tests, the materials listed in Table III-2 were recommended for further testing. This choice was based on resistance to the environments and judgment of the relative ease of seam formation. However, the preliminary results of D-value testing performed by NASA Goddard indicated that initial estimates of required temperature conditions were low. Therefore, all materials were eliminated from consideration except for 2- and 5-mil thicknesses of FEP. A composite material meeting the temperature limitations, consisting of a sandwich of 1-mil FEP, 3-mil Kapton, and 1-mil FEP, was eliminated due to extreme difficulties in splitting the seam by any means other than a motorized cutting wheel. The potential aerosoling of bacteria with such a tool was considered to be unreliable. Also, several tests indicated possible delamination of the composite during sealing. Additional testing of the 2- and 5-mil FEP film was requested by NASA. In addition, vendors were requested to investigate any additional possibilities or experimental films under development by film manufacturers that could offer higher sealing temperatures.

Table III-2 Midterm Review Material Recommendations*

1. ACLAR 33C - 5 mil
2. KAPTON HF (FEP/H/FEP) - 5 mil
3. FEP - 2 mil
4. FEP - 5 mil
5. MYLAR 75 M-22 - 3 mil
6. KYNAR - 2 mil
*In order of preference

C. EVALUATION OF NASA SELECTED MATERIALS

1. General

Tests conducted during the second half of the program were selected to evaluate various properties of the NASA-recommended materials. These properties were chosen for their relationship to design application and environmental stability. The tests listed below are discussed in detail in the paragraphs that follow.

Sealability and fusion	Transparency
Resistance to sterilization	Formability
Seam strength	Flexibility
Burst strength	Film attachment

2. Sealability and Fusion Tests

a. Discussion

Evaluation of the heat-sealing properties of the films tested is of extreme significance in terms of relating the thermo-physical conditions present at the seam to the reliability of the seam formation process, especially from the biological standpoint. While the biological considerations were not studied in this program, the development of suitable heat-sealing parameters for the selected materials will provide a baseline for future biological/mechanical relationship studies.

- 1) Equipment - The equipment used for evaluation of the sealing properties was a modified Vertrod Inc., Model 18C, (Fig. III-3). This apparatus was modified to provide time, temperature, and pressure data.

A mechanical microswitch on the original equipment was activated when the jaws were clamped. To ensure that the films were properly aligned before initiating the cycle, and to establish a known start time for the cycle, this microswitch was provided with an override to permit operator switching. This override also permitted extension of the heating cycle time beyond the normal time for this equipment, thus extending its ability to seal up to 650°F and to seal thicker films.

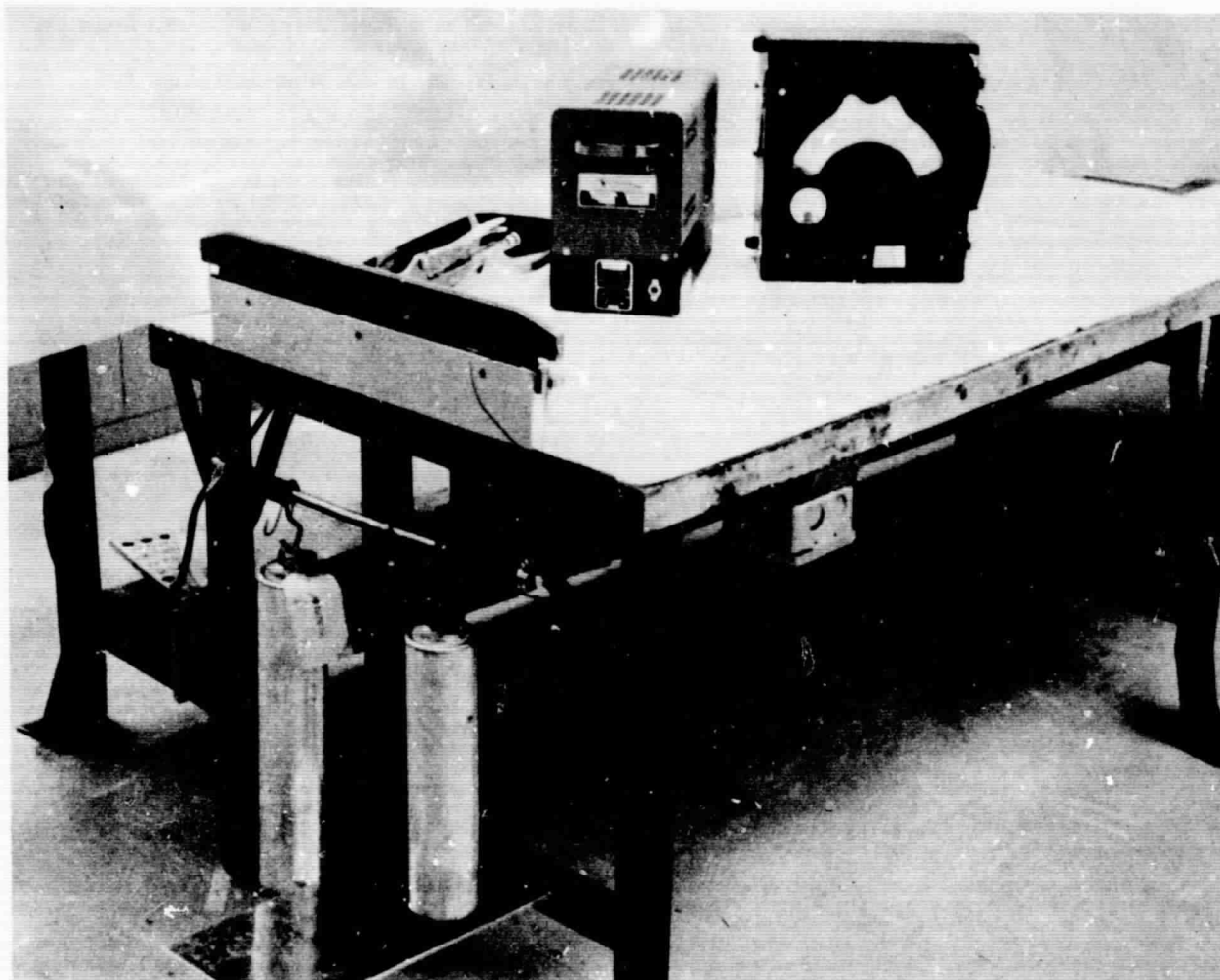


Fig. III-3 Heat-Sealing Apparatus

- 2) Pressure determination - Determination of the pressure on the heat-sealing area is based on preloading the upper bar through a cable suspension arrangement with calibrated weights. The load (psi) on the sample is calculated for the weight and the pressure-pad surface area. In this case, the surface area of the pads is 5.6 square inches. When increments between available calibrated weights were required for specific psi increments a treadle plate and fish scale calibrated to ± 1 lb were used to apply the additional load. The load increments investigated are listed in Table III-3.

Table III-3 Sealing Pressures

<u>Weight (lb)</u>	<u>Load (psi)</u>
34	6.1
49	8.75
56	10.0
70	12.5
84	15.0
98	17.5
112	20.0
126	22.5
140	25.0

- 3) Temperature determination - Temperature determinations were made by a 30-AWG iron-constantan thermocouple using a Lewis potentiometer to track the temperature increase during the heat cycle. The thermocouple was located between two layers of Dupont Kapton (H-film), 1/2 mil thick. To evaluate the effect of the H-film thermal conductance on the measurement of the temperature at the seam interface during sealing, a series of temperature calibration runs was made. Each of these calibrations used a thermocouple placed at the interface of an actual seam. Comparisons of the heating rates and maximum temperatures for a range of cycle dwell times was then made. The use of the H-film produced approximately 45°F lower temperature indication at the sealing range. This difference has been calculated into all temperature data presented in this report.

Because of the very high temperature required by this program, it was necessary to replace the TFE/glass laminate covering the sealer heating strip with a layer of Kapton H-film. The FEP films adhered to the TFE/glass laminate during a normal sealing cycle. The Kapton material is a nonheat-sealable polyimide film that vendor data indicates will withstand temperatures up to 800°C. Small additional strips of the H-film were cut and placed on each side of the heater strip to eliminate the shearing action generated by the upper pressure pad pushing the tested films down on each side of the strip. The overall H-film cover sheet then presented a flat surface to support the film. This improvement in the equipment was necessary to successfully seal the films investigated.

The rubber pressure pad supplied with the sealer was also replaced to provide a higher temperature capability. A silicone pad was cast from a silicone material in use at Martin Marietta, supplied by Chem Seal Corp. (CS 3808). The base polymer of this material has been used in formulations of spacecraft ablative coatings. The cast material has a hardness of approximately 60A Durometer. This material provides up to 10 hours of operation at temperatures above 450°F.

b. Specimen Preparation

Evaluation of the results of the screening program indicated that testing of seamed material provided more consistent data when a peel-type test configuration was used instead of a lap-shear type. This is believed to be due to the greater difficulty in aligning the sample sheets during sealing and subsequent cutting into test width in the case of the lap samples. Furthermore, analysis of the general design concept (Fig. I-1) reveals that, in the actual case, the type of seam formed does produce a peel-type joint. For this reason, only representative data of the lap construction were taken to evaluate seam strength. (See subsections 3.b. and 4.b. of this chapter.)

The configuration used for formation of sealability test seams consisted of film samples 3 1/2 inches wide by 5 inches long. For peel samples, two sheets were overlaid and aligned. The seam was then formed using the condition selected for each test along the length of one edge, with the inside edge of the seam 1/2 inch

from the material edge. This sample was then cut using a die accurate to ± 0.003 inch into five strips, one inch wide, thus producing five samples for each time/temperature/pressure relationship investigated. The lap samples were similarly prepared except that the two $3\frac{1}{2} \times 5$ sheets were only overlapped $\frac{1}{2}$ inch on the long dimension and the seam formed in the lapped area.

c. Seam Test

Seams were formed to establish the optimum sealing conditions by a matrix of the following conditions for both 2- and 5-mil FEP:

Time/Temperature* (sec) (deg)		Pressure (psi)
3 to 5	375	6.5
3 to 6	400	10.0
4 to 7	425	12.5
5 to 8	450	15.0
6 to 8	475	17.5
7 to 9	500	20.0
8 to 10	525	22.5
10 to 12	550	25.0
*Time is proportional to maximum temperature		

The seams were immediately inspected visually to detect any air pockets, inclusions, or obvious lack of fusion. The sheets were then cut to the 1.0-inch widths with surgical scalpels and the die forms. Samples were again inspected to ensure that no nicking, notching, or scribing of the sample had occurred during the cutting operation.

All samples were then pulled in the BLH tensile machine at a rate of 20 inches/minute elongation. The ultimate load (pounds/inch of width), approximate elongation, and description of the mode of failure were indicative of the degree of fusion and thinning of the material during the sealing cycle. Notably, the samples that had little or no fusion (usually below 425°F) would actually separate at the original interface. As fusion increased, the failures were noted to approach the outer edge of the seam area until, within a range of temperatures, the maximum strength was maintained. Excessive heating and associated thinning of the material showed up as failures just outside the seam area and frequently started as a hole popping in the film just before total failure.

d. Sealability results

The sealability tests indicated that the temperature is the most important factor in achieving seams of optimum strength. No adequate seals of FEP were obtained at temperatures below 450°F. This agrees with vendor data on sealability. Up to 525°F, there is an improvement in the seam strength, after which excessive heating will tend to degrade the quality of the seam. Comparative data for these seams appear in Fig. III-4 through III-7. Evaluation of these data provided the basis for selecting the following sealing conditions.

The optimum conditions for sealing 0.002-inch FEP film are 7 to 10 seconds, at a pressure of 22.5 psi, within the range of 500° to 525°F.

The optimum conditions for sealing 0.005-inch FEP film are 8 to 12 seconds at a pressure of 25 psi, within the range of 500° to 525°F.

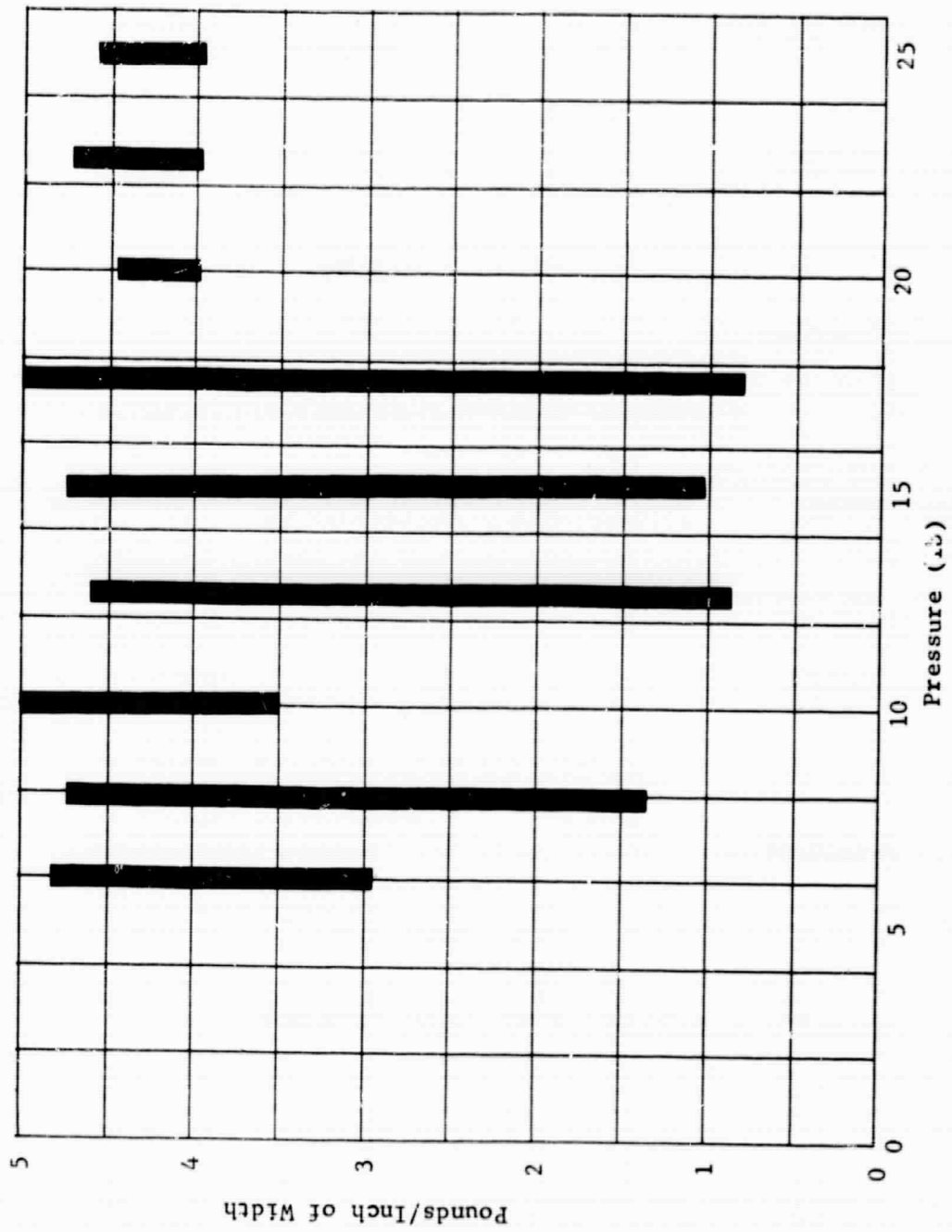


Fig. III-4 Seam Strength versus Pressure (2 mil FEP)

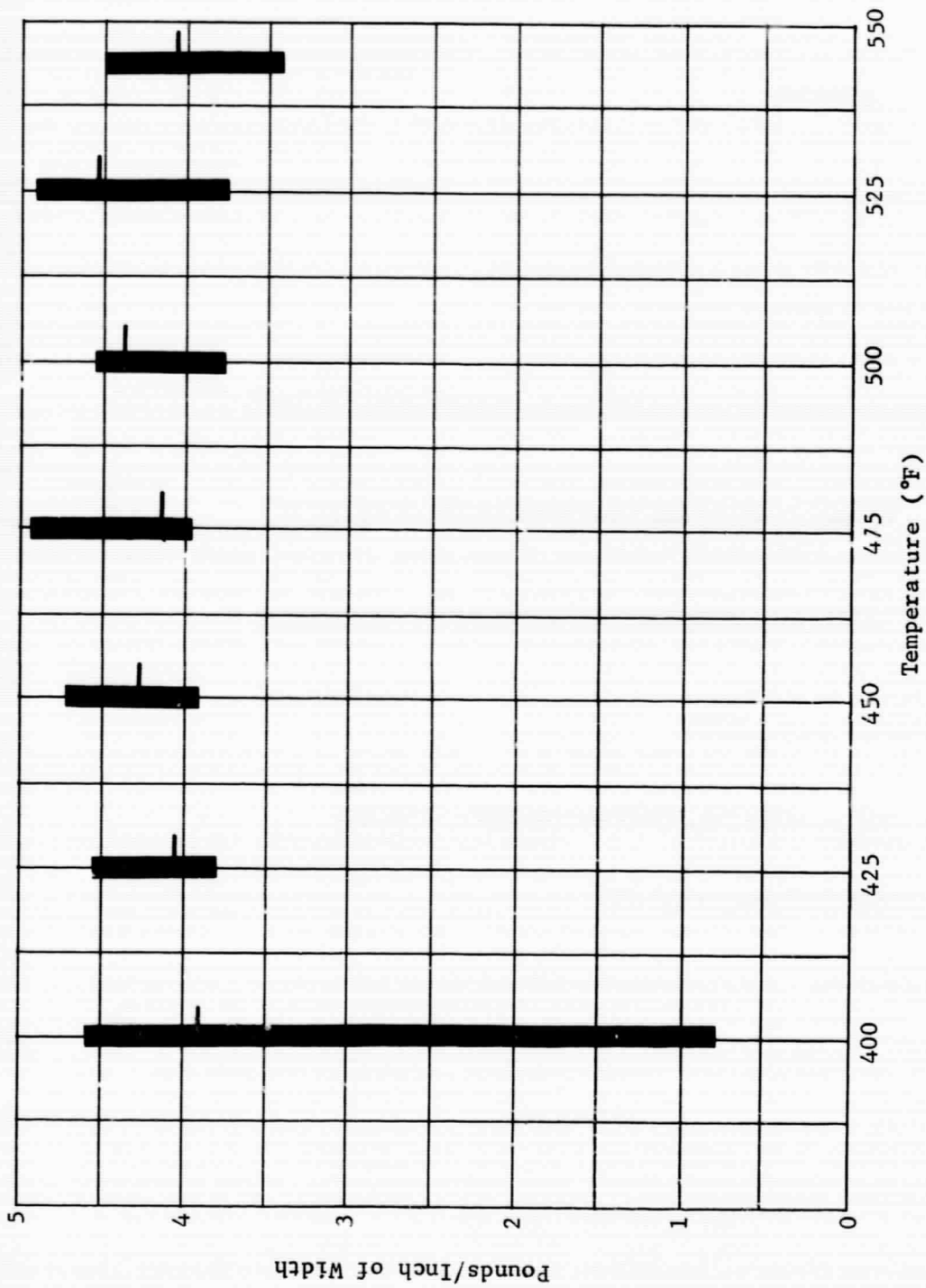


Fig. III-5 Spread and Average Seam Strength versus Temperature (2-mil FEP)

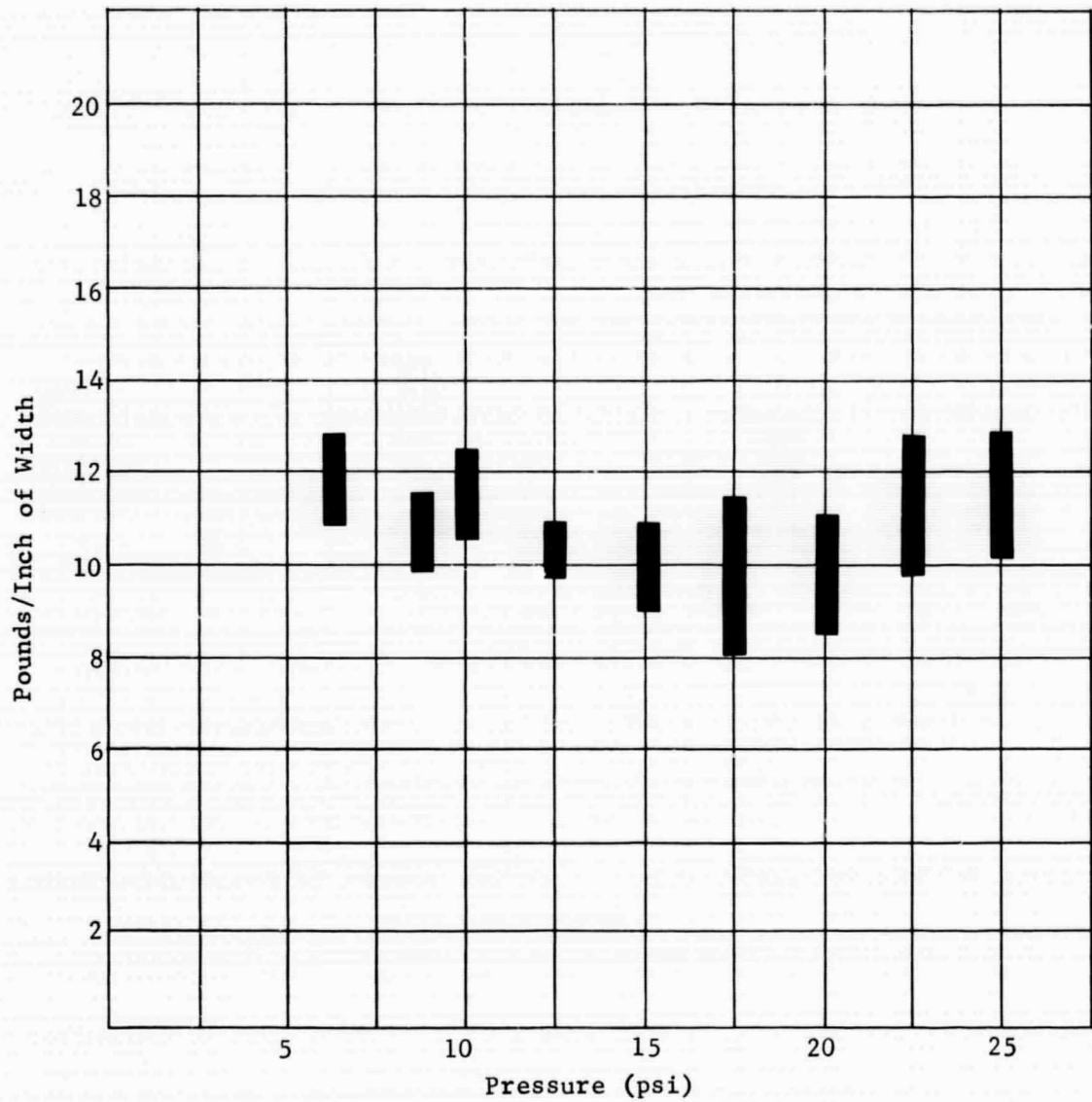


Fig. III-6 Seam Strength versus Pressure (5-mil FEP)

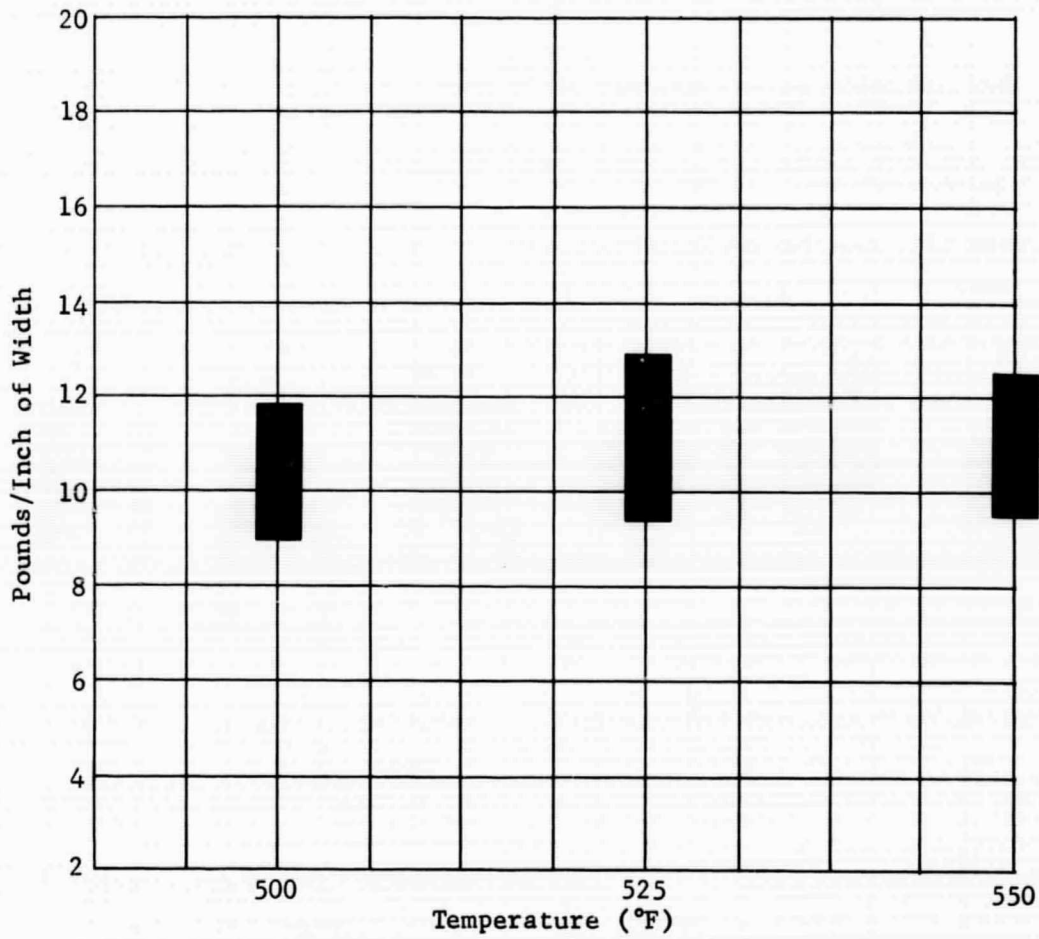


Fig. III-7 Seam Strength versus Temperature (5-mil FEP)

3. Resistance to Sterilization Environments

a. Discussion

The design concept for sterile insertion requires that the plastic biological barrier through which such a penetration would be made must withstand all the same elements of sterilization processing to which a planetary probe or canister, upon which the barrier is mounted, will be subjected. Due to existing requirements for reduction of the probability of biological contamination to a 10^{-3} level, an initial ETO/Freon 12 decontamination procedure for reduction of surface bacterial count to a working level is performed before final sterilization by an extended elevated-temperature cycle. The procedures for performance of the environmental exposures evaluated in this portion of the program appear in subsection A2 of this chapter.

b. Samples

The results of sealability/fusion testing provide an indication of the optimum range for fabrication of seams from material that has been exposed to the sterilization conditions. The samples for exposure therefore consisted of 5-inch by 5-inch by thickness sheets for tensile tests, and 3 1/2-inch by 5-inch by thickness sheets for seam tests. Subsequent to environmental (ETO and heat) cycling the 3 1/2-inch wide samples were paired in various combinations with exposed and parent (original) material for seam formation.

c. Tensile Tests

Comparison of the effect of ETO and heat exposure on original (or virgin) material tensile properties was repeated, in spite of tests originally run in the screening portion of the program, for two reasons. First, to reconfirm the effect of sterilization on the basic strength of the material, and second, to ensure that the environmental cycles were providing the same test history for parent and seam samples. The 5-by-5-inch samples mentioned above were used for this evaluation and cut into five 1.0-inch-wide samples for tensile testing. The tensile test was conducted at a rate of 20 inches per minute elongation. Comparison of the additional data gathered at this point shows good correlation with the original parent test data from the screening tests.

d. Seam Tests

The effect of the sterilization procedure on seam strength was evaluated in terms of the change in peel strength. The seamed samples were prepared in the following combination: ETO/heat-exposed film seamed to ETO/heat-exposed film, ETO/heat-exposed film to parent (unexposed) film; and, for a control measure of the seaming operation, parent-to-parent films.

Seamed samples of two ETO/heat-exposed samples correspond to the projected case of the plastic barrier being mated to a service bag that has been sterilized as a whole by exposure to ETO and heat. Seamed samples from parent and sterilized films are partially representative of mating a service bag, sterilized by other means than ETO or heat, to the sterilized spacecraft.

The conditions under which samples were sealed for the seamed test were selected from the results of similar tests on parent (unexposed) seams. The range of seam formation conditions used includes those producing the best physical seams for parent films. Results of the tests indicate that no significant difference in sealing capability or degradation of physical strength resulted from exposure of the 0.005-inch FEP film to the ETO decontamination and terminal heat cycle conditions. A reduction of physical strength of approximately 5% was observed in the 0.002-inch film. This reduction may be partially related to a greater difficulty in alignment of the exposed 2-mil films for seaming and sample cutting due to a curling tendency of the thinner film. See Fig. III-8 for a graphical presentation of the sterilization resistance data.

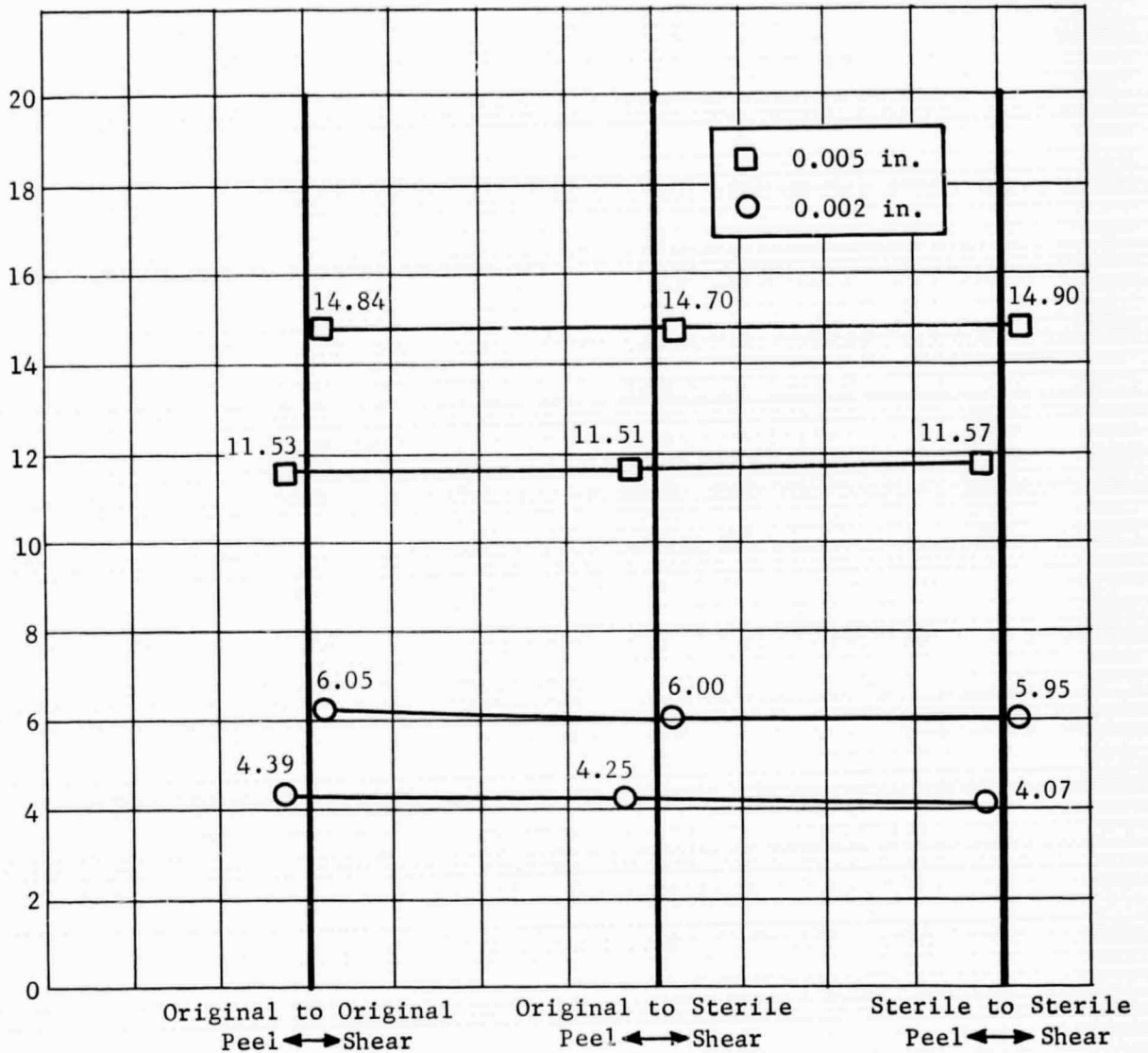


Fig. III-8 Sterilization Resistance (FEP)

4. Seam Strength Tests

a. Discussion

The evaluation of the strength of seams formed under these time/temperature/pressure relationships included both peel and lap shear heat-sealed seams. As previously discussed, the most consistent data were obtained from the peel configuration samples. The shear strength samples were included to assist in evaluating the degradation effects on the film, i.e., the optimum strength to be expected from a seamed joint will not be equal to the unseamed material due to reduced film thickness in the seamed area.

b. Samples

The test samples evaluated consisted of:

- 1) Control samples used for the sterilization resistance tests;
- 2) Samples formed under the best conditions for sealability evaluation;
- 3) Additional shear tests prepared especially for this test.

Sample configurations were as described in subsection 3.b.

c. Results

The comparison of results of tests of seamed material indicates that peel loading of the seam will yield strengths approximately 35% of the original material, while shear strengths range from 2% to 30% of the original material. A more complete presentation of these data appears in Fig. III-9.

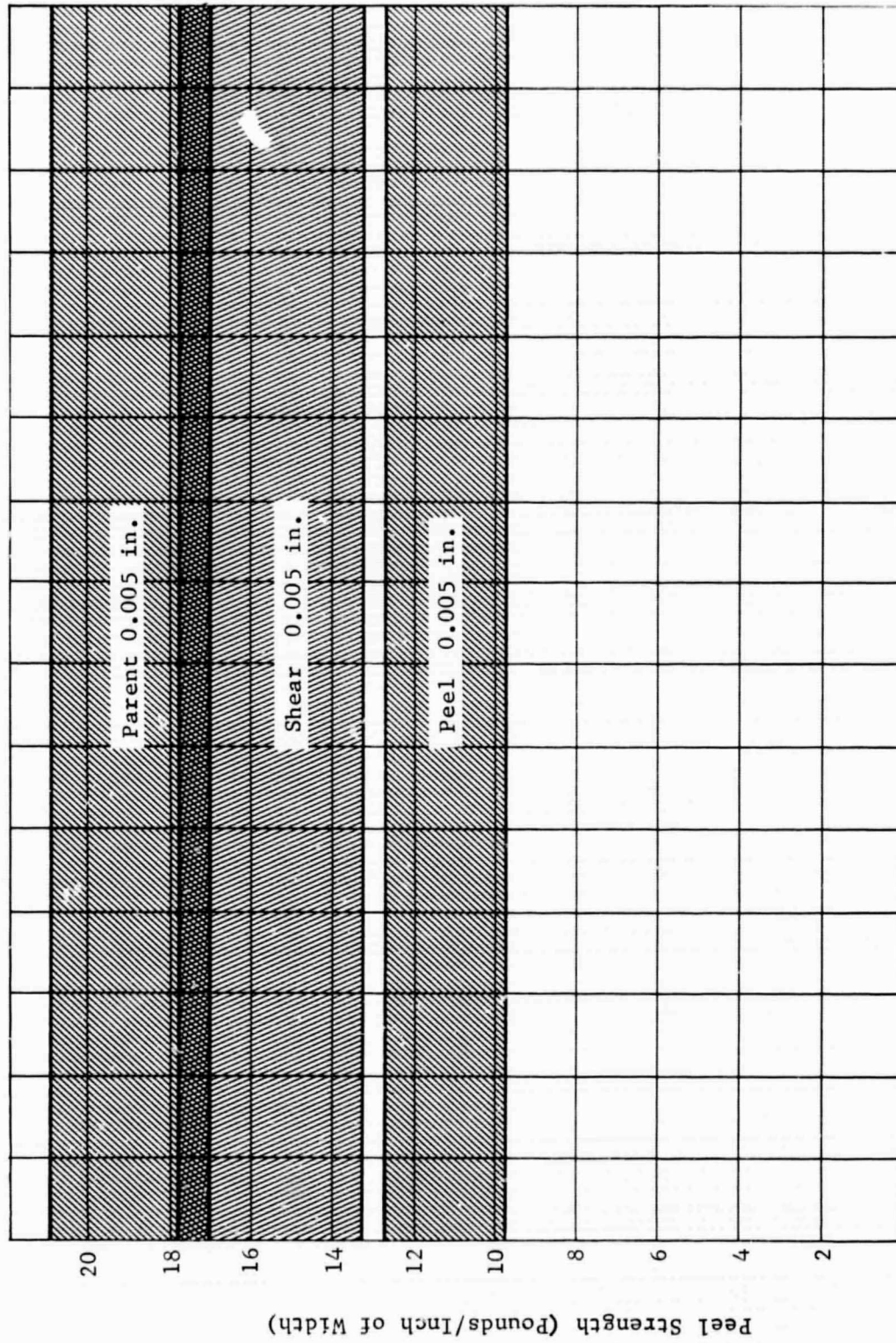


Fig. III-9 Peel Strength Comparison of Seam to Parent Material

5. Burst Strength Test

a. Discussion

The burst strength of the plastic barrier film required evaluation because of pressure changes within a sealed spacecraft during terminal heat sterilization due to expansion of the heated gases. While this pressure will be held to 2 psi within the spacecraft by relief valves, a higher pressure may result from the gas trapped between the film and the canister hatch. Therefore, a burst fixture was designed and fabricated as described below. These tests were conducted with air and with N_2 as the pressurizing gas because, depending on the port/barrier design, the gas in contact with the film could be either air or N_2 .

b. Burst Fixture

The burst fixture designed for this test is shown in Fig. III-10. This unit is designed so that the films being tested serve as a primary gasket. A silicone rubber gasket is the final seal. The arrangement for clamping the specimens prevents a circumferential shearing force being applied to the edge of the sample. The open space on the low-pressure side of the film permits observation of the film during the pressurization sequence.

c. Test Procedure

Six-inch-diameter discs of the 2- and 5-mil FEP film were tested. Both films were tested as parent material and sterilization-cycled material. In addition, tests of each of these conditions were performed at ambient and sterilization temperatures (125°C). The procedure was performed in the following sequence:

- Position sample in fixture and secure threaded clamp;

- Attach pressurization line to fixture inlet;

- When an in-line dessicator is used to ensure that the pressurization gas is dry, it is pre-baked at 250°F for eight hours for drying before installation;

- Stabilize the fixture at the test temperature for 30 minutes, minimum;

- Initiate pressure increase with required gas by applying at a rate of 1/4 psi increment per minute until 2 psi is reached;

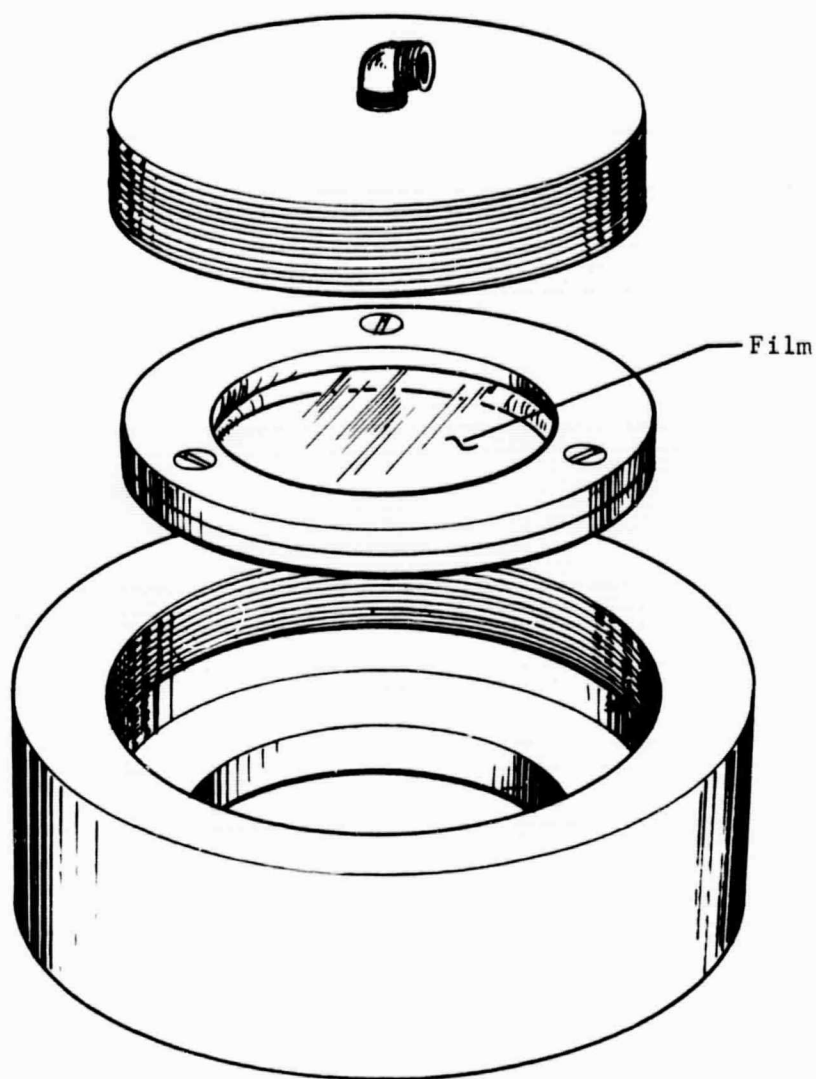


Fig. III-10 Burst Fixture

Hold the pressure at 2 psi for 5 minutes;

Continue pressure increase at 1/4 psi per minute until rupture or a sharp decrease is noted;

Remove sample with fixture at room temperature;

Inspect sample visually to establish the mode of failure.

The pressurization gases used were 99% N₂ and K-bottle dry air.

In both cases the gas was passed through a cold trap and in-line dessicator before being introduced to the fixture. Pressure increments were monitored by a ± 0.05 psi gage. Temperature was monitored by a thermocouple placed on the fixture next to the film attachment.

d. Test Results

The tests performed indicated a significant reduction in the burst strength of both 2-mil and 5-mil FEP due to temperature. No significant changes due to exposure to the sterilization environments were established. The reduction in strength of the FEP films indicates that the 2-mil FEP would rupture in the actual application if unsupported. The 5-mil film would be borderline at best in passing a 2-psi differential pressure. In both cases, a permanent distortion of the film occurs due to the stretching of the film. The burst data are presented in Table III-4.

Table III-4 Burst Test Results

Material	Condition	Thickness (mil)	Test Temp (°C)	Max Pressure (psi)	Remarks
FEP	Parent	2	25	3.0	
		2	125	1.0	
FEP	Parent	5	25	8.5	
		5	125	3.50	
FEP	Sterilized	2	25	3.0	No failure jig seal lost
		2	125	1.0	
FEP	Sterilized	5	25	8.0	
		5	125	3.25	
Kapton HF (1/2-3-1/2)	Parent	4	25	17.25	
		4	125	19.0	
Kapton HF (1/2-3-1/2)	Sterilized	4	25	18.25	
		4	125	19.0	

6. Transparency Test

a. Discussion

The transparency of the 2- and 5-mil FEP films and two thicknesses of Kapton HF composite were established by two means -- measurement of the percent of light transmission and visual judgment of clarity or resolution. Samples were evaluated before and after exposure to sterilization environments.

b. Percent of Transmission

Samples of the film were placed in the beam of a Beckman DK-2A spectrophotometer. Compared to 100% transmission with no sample, one and two layers of the film were inserted successively and the percent of transmission noted. The light source was a 5500 Å monochromatic beam, which is the approximate center of the visual spectrum.

c. Visual Inspection

Samples of 1-mil, 2-mil, and 5-mil FEP and 2-mil and 4-mil Kapton HF were subjected to the sterilization procedures. These samples were then used to compare visual observations of clarity to unexposed samples of the same film. Two layers of the film were placed over a standard Printers Style Reference Chart and the ease of reading the type established. The point size indicators were used as a measure of clarity.

d. Results

1) Percent Transmission

No significant change in the transmission of light through the films was detected as a result of exposure to the sterilization environments. See Table III-5 for light transmission data for films evaluated.

2) Visual Clarity

No reduction in visual resolution was noticed for 1 or 2 layers of the tested films down to 2-point type (the smallest type on the chart). In addition, no difference between parent and sterilization-exposed films was detected.

Table III-5 Transparency Test Results (% Transmission)

Material	No. of Layers	Original	After Sterilization
FEP - 1 Mil	1	93.5	92.5
	2	88	86
FEP - 2 Mil	1	94	92
	2	87.5	87
FEP - 5 Mil	1	90.5	92
	2	82	79
Kapton HF (1/2-1-1/2)	1	81.5	82
	2	66	68.5
Kapton HF (1/2-3-1/2)	1	60	61
	2	40	35.5

7. Formability Test

a. Discussion

Design Concept "A" described in Chapter II offers advantages based on a capability to form (or shape) the material used for the plastic barrier to the shape of the sealing track. Evaluation of the effect of forming the barrier material on its sealing and physical properties is important to ensuring the design feasibility of the concept. Forming of films generally requires a reduction in film thickness in the formed region.

b. Equipment

A fixture for use in the evaluation of the formability of films was designed and fabricated. This device provides a method for peripheral clamping of a disc of the material in a circular window frame. A close-fitting die is pushed into the frame to form the material. The depth of draw is approximately 5/8 inch.

c. Test Procedures

The material tested included only the 2- and 5-mil FEP. No tests were conducted using Kapton HF because the polyimide inner film of the composite is both non-heat sealable and non-heat formable.

The FEP film was mounted in the frame and then placed in an oven at the forming temperature. When the jig reached temperature, the die, which was mounted on guide pins, was allowed to press on the film with its own weight. The jig was held at temperature until completely closed. After cooling, the part was inspected for sidewall thickness and any holes or failures in the film. Forming temperatures of 475°F, 500°F, and 550°F were investigated by this method.

d. Results

None of the film forming tests of 2- and 5-mil FEP resulted in an acceptable formed part using the method described above. The 2-mil film stretches to the point of tensile failure almost immediately upon application of the die load at all temperatures. The 5-mil FEP film stretched without failure to a depth of 1/4 inch, but the weight of the die would not carry the die to the full formed dimension. Application of additional load to the die then

caused edge failure of the film at all three temperatures. Analysis of the samples indicated that the majority of the stretching was occurring in a band only 1/8 inch wide. Because the elongation of the material was generally no more than 200%, a 1/2-inch draw of this material can rupture the film. To alleviate this problem, a modification of the fixture was made to permit application of the forming force with air pressure against a female die. The results of this test indicate that the 5-mil FEP can be formed, but the film is significantly reduced in thickness. Test results showed that draw depth was increased but at the expense of film thickness around the critical radius region. To minimize this problem, another approach was tried using an unclamped forming concept. As shown in Fig. III-11, this technique yielded an acceptable formed specimen to the full die depth of 5/8 inch and 3-inch diameter. Additional work will probably be required during the follow-on development phase to obtain acceptable plastic barriers for the 3/4 inch depth, 18-inch diameter design application.

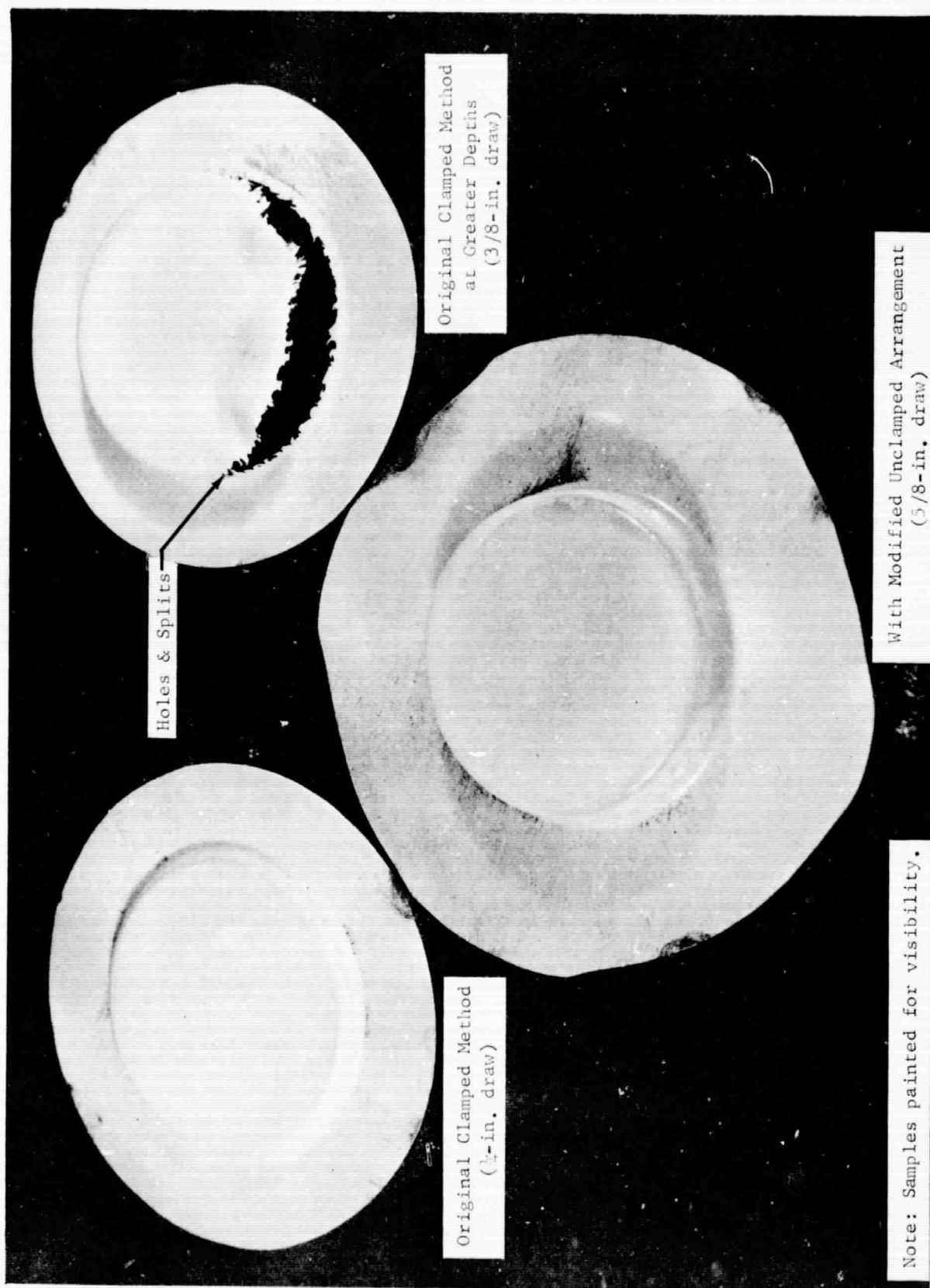


Fig. III-11 Formability Samples

8. Flexibility Test

a. Discussion

The handling of these films in the forms of spacecraft barriers and service bags indicates that the flexibility of the films over a range of ambient operating conditions may affect the ease of application. To evaluate the material, samples of the 2- and 5-mil FEP films were subjected to a flexibility test at the limits of ambient temperature to be expected, 40°F and 120°F.

b. Test Procedure

One-inch-wide samples of each film were stabilized at the test temperature for 30 minutes. The samples were then bent (or folded) 180° around a 1/4-inch mandrel and a 1-lb weight suspended from the film.

c. Results

1) 40°F Test

Five samples of the 2- and 5-mil films were tested. No sign of brittleness, cracking, crazing, or damage to the film was observed.

2) 120°F Test

No degradation of the film was observed at the bend radius. At the point where the alligator clip supporting the weight was attached to the film, there was a tendency to stretch the film slightly and puncture it. This points up the requirement that no sharp or pointed items be allowed to contact the film barrier.

9. Film Attachment Test

a. Discussion

Discussions with technical personnel from the Dupont Company indicated that the available techniques for adhesively bonding FEP films to any substrate require the surface of the FEP to be specially treated with a sodium-based etching compound. These compounds are available in several **proprietary** forms from licensed vendors, such as Shamban, Inc., and Joclin Manufacturing Company.

b. Test Results

As shown in Table III-6, acceptable adhesion is retained after exposure to heat sterilization but exposure to ETO/Freon 12 causes loss of adhesive properties. Although this characteristic will not affect performance of the recommended configuration (i.e., the plastic barrier is not exposed to ETO/Freon 12), a method of adhesion without these constraints would be needed if pursuit of alternative configurations were contemplated in the future.

To meet this projected need, a small-scale evaluation was conducted of a hot-gas welding technique for melting the material onto the surface to achieve adhesion. As shown in Table III-7, peel samples prepared by this technique showed a range from 0 (no adhesion) to 2.5 lb per inch of width. This wide variation appears to stem from the lack of precise temperature controls in the test setup. It is believed that further development work can affect a hot-melt technique suitable for use with substrates able to withstand a 700°F temperature.

Table III-6 Effect of Sterilization on Adhesive Strength

Material	Original Value (psi)	After ETO/Freon 12 Exposure (Lap Shear in psi)	After Heat (600 hr at 135°C) (Lap Shear in psi)
Hysol 1-C	1000	760	2440
Armstrong A-6	780	545	2376
Devcon F	530	500	3910
Dow Corning 93-046	160	135	227

Table III-7 Hot Gas Adhesion Peel Strength (180° peel)

Sample No.	Surface Preparation	Peel (lb/inch)
1	Sanded 320 & solvent cleaned	2.2
2	Sanded 320 & solvent cleaned	0.7
3	Sanded 320 & solvent cleaned	2.5
4	Sanded 320 & solvent cleaned	0
5	Sanded 320 & solvent cleaned	1.6
6	Solvent cleaned	1.2
7	Solvent cleaned	0.3
8	Solvent cleaned	0
9	Solvent cleaned & glass reinforced	1.8
10	Solvent cleaned & glass reinforced	0

D. CONCLUSIONS

Both 2-mil and 5-mil FEP film sealed at conditions compatible to the design concepts developed.

The sterilization environments of ethylene oxide decontamination and terminal-heat sterilization do not affect FEP films.

The 2-mil FEP film does not withstand the anticipated pressure differential across the barrier due to gas expansion during the terminal heat cycle. The 5-mil film does withstand the 2-psi differential but shows failure at levels only 50% higher. This marginal property, however, may not be significant for application to the recommended design configuration. The dual-cover arrangement in this design yields minimum entrapped air, tends to balance internal pressure by air entrapment on both sides of the plastic barrier, and uses the cover on the side with the least entrapped air as a support against expansion of the film.

No problems are anticipated from a visual handling of either one or two layers of the films, nor from a flexibility standpoint.

Excessive reductions in film thickness were noted when standard forming techniques were used with FEP films. Modifications of these techniques yielded acceptable forming to depths of over 1/2 inch by 3-inch diameter, but ruptures occurred before the present design dimension of 3/4 inch. Further work is required to obtain formed FEP parts with the required 3/4-inch depth and 18-inch port size.

Present adhesives for FEP-to-aluminum substrates show satisfactory properties after heat sterilization but unsatisfactory adhesion after exposure to ETO/Freon 12. Hot-gas adhesion gave inconclusive results. Although no problem is posed for application to the recommended configuration, further work is required if other concepts are considered for development.

IV. RECOMMENDATIONS

After careful evaluation of all the conceptual designs presented in this study, sterile insertion techniques can be considered well within the state of the art. However, a considerable amount of work still remains before an operational sterile insertion technique is achieved. The Martin Marietta Corporation submits the following recommendations to achieve this technique based on the data and design concepts presented in this report:

- 1) Initiate a detailed engineering, development, and test program. This program, as a minimum, should yield working models of the self-propelled heat-sealing and cutting tools (Fig. II-24 and II-30), along with an 18-inch diameter model of the sterilization canister entry port, and the corresponding service-bag assembly illustrated for Design Concept A. The tools should be tested for performance by using the entry port and service bag models.
- 2) Develop a manual heat-sealing tool. This tool would be used as a repair or finishing tool for imperfect spots that may accidentally appear in the heat seam produced by the self-propelled tool. This manual tool should be developed using the design of the wheel-type, roll-on heat-sealing tool illustrated in Fig. II-17. However, the handle should be placed 90° to the wheel. This change will make tool application on the sides of the heat-sealing rail much easier.
- 3) Develop techniques for seam inspection. These techniques are necessary to ensure that a perfect seam is obtained before the cutting operation is initiated.
- 4) Initiate a reliability test program using a challenge system to determine reliability of the entire sterile insertion operation. A challenge system is recommended that uses a double isolator system containing an inner sterile isolator surrounded by an outer isolator enclosing the challenge environment.

- 5) Develop sterilization procedures for the tools and service bag. These sterilization procedures should be based on data obtained from a materials compatibility test program designed to evaluate the compatibility of the materials of the tools and service bag with the ethylene oxide/Freon 12 mixture, the dry heat sterilization temperature, and other methods of sterilization.
- 6) Perform additional material development work to extend formability capability to the 3/4 inch depth, 18 inch diameter, model size; and establish reliable film attachment materials and processes for the original plastic barrier.

APPENDIX

SCREENING TEST DATA

Table A-1 This table contains data comparing the original tensile strength of candidate materials with strength after exposure to the environments discussed in Chapter III, Section C.

Table A-2 This table contains data on peel strength samples of materials selected from the tensile strength results.

Table A-1 - Tensile Test Data

Material	Thickness (in.)	Parent Tensile Values (lb)					Avg	Sterilized Tensile Values (lb)					Avg	Remarks
		1	2	3	4	5		1	2	3	4	5		
HE-Ben P.E.	0.006	--	--	--	--	--	--	Destroyed by heat					--	No test run
Lo-Ben P.E.	0.005	--	--	--	--	--	--	Destroyed by heat					--	No test run
KYNAR	0.001	3.45	4.6	4.0	3.5	3.6	3.8	1.9	3.2	2.7	2.4	3.7	3.0	
KYNAR	0.002	12.9	10.0	11.9	10.7	12.9	11.6	13.7	13.1	13.2	13.2	11.5	12.7	
POLYCARBONATE	0.002	16.15	16.80	18.30	15.85	17.80	16.95	16.80	16.65	16.60	--	--	16.7	Poor heat stability
MONOLITE S	0.006	18.1	28.75	31.55	31.95	29.65	27.90	30.25	30.60	30.00	31.00	30.20	30.50	Very brittle
LEXAN	0.001	10.3	9.95	10.80	9.40	6.90	9.50	5.70	1.80	5.15	3.10	0.50	3.25	Brittle
LEXAN	0.005	44.8	52.1	54.4	55.8	56.9	52.8	46.4	43.5	43.0	38.0	43.4	42.3	Embrittled
LEXAN	0.010	100.6	113.5	112.1	125.0	106.2	111.5	26.75	21.60	24.30	23.95	27.95	25.11	Loss of strength
TEDLAR S	0.002	--	--	--	--	--	--	Destroyed by heat					--	No test run
CAPLAR 77C	0.005	61.0	34.4	36.6	38.0	38.0	41.6	57.0	54.6	56.5	56.0	57.5	56.3	Some brittleness
CAPLAR 77C	0.010	77.9	78.4	75.1	77.2	120.0	85.5	122.4	121.6	121.5	126.2	123.5	115.4	Brittle
ACLAR 22A	0.005	28.9	32.2	30.2	25.9	29.0	29.04	23.75	23.80	22.90	23.10	23.45	23.40	Slightly brittle
ACLAR 22C	0.005	25.25	25.40	25.15	24.90	24.50	25.04	27.85	25.40	28.2	14.25	27.10	20.3	Slightly brittle
ACLAR 32C	0.005	26.70	26.95	26.65	27.0	26.20	26.70	26.05	27.05	26.70	26.90	27.05	26.75	No change
MYLAR 75	0.003	20.00	15.15	19.90	19.40	13.10	16.53	16.30	21.25	16.70	9.20	14.60	15.13	Some loss of strength
MYLAR MF	0.005	86.0	85.5	97.4	96.0	93.3	90.0	89.0	89.3	90.0	89.0	89.3	89.3	
PEP	0.002	8.30	7.55	8.47	6.95	7.45	7.78	8.65	8.65	7.95	7.60	6.15	7.80	No change
PEP	0.005	14.90	14.75	18.90	19.60	17.50	17.13	18.0	21.50	16.80	11.40	18.05	17.15	No change
POLYSULFONE	0.005	43.1	46.0	43.8	47.5	44.0	44.9	47.0	44.2	45.1	45.0	44.5	45.1	Brittle

Table A-2 - Peel Test Data

Material	Thickness (in.)	Parent Peel Strength					Avg	Sterilized Peel Strength					Avg	Remarks
		1	2	3	4	5		1	2	3	4	5		
PEP	0.002	4.36	4.10	4.10	4.39	4.10	4.21	4.10	4.25	4.20	4.32	4.22	4.21	No change
PEP	0.005	10.7	11.35	11.30	11.10	11.00	11.09	10.90	10.20	11.10	12.0	11.35	11.11	No change
MYLAR MF	0.005	Samples delaminated						--	--	--	--	--	--	Need further test
KYNAR	0.001	2.30	3.60	2.05	1.85	2.30	2.42	3.40	2.75	2.90	3.05	2.60	2.94	Stiffer
KYNAR	0.002	5.9	5.3	4.75	4.90	7.0	5.37	7.0	6.15	7.40	5.80	5.80	6.43	Brittle
MYLAR 75	0.003	11.90	11.10	12.10	13.90	12.25	12.25	8.75	9.30	8.80	8.20	9.15	8.84	Loss of strength
ACLAR 32C	0.005	Insufficient material for sample preparation												