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Fifty-nine pairs of sterile docking tabs, manufactured by the Jet Propulsion Laboratory, Pasadena, California, were tested for maintenance of sterility. The tabs were contaminated with known amounts of Bacillus stearothermophilus, sealed, and flushed with sterile culture medium. Twenty-five percent of the seals failed because of mechanical weakness. Of the remaining 75% of the docks, 93% remained sterile. While the concept of the tabs is promising, more work needs to be done on their mechanical design to increase strength.

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TECHNICAL NOTE NO. 82-39TN

STERILITY TESTING OF PROTOTYPE PLASTIC ASEPTIC DOCKING TUBES

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Sterility Testing of Prototype Plastic Aseptic Docking Tubes
--Moore and Jederberg

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STERILITY TESTING OF PROTOTYPE PLASTIC ASEPTIC DOCKING TUBES
—Moore and Jederberg

Several products being developed in our division could be easily adapted to field use if technology existed to make sterile liquid transfers between plastic bags of physiological fluids or between plastic bags of freeze dried materials and portable USP water generators.

A simple "sterile docking device" using polyether sulfone, polyvinyl chloride (PVC) and other plastics has been designed by the Jet Propulsion Laboratory (JPL), Pasadena, California. It is referred to as a flat "aseptic fluid transfer system," (AFTS). This device is compatible with plastic bags or other types of plastic biomedical plumbing equipment. The AFTS consists of a small plastic pouch, or tab, about 1 x 2 1/2 inches (2 x 6 cm) in size, sealed on all sides, with a PVC plastic tube extending from one end. For developmental purposes this tube is attached to a 20 gauge hypodermic needle (Fig. 1). One of the inner surfaces of each tab has a high melting plastic bonded to it. In use, two tabs are overlayed such that the high melting plastic surfaces are exterior to the two mated surfaces. The tabs are placed in a radiofrequency (RF) sealer which melts the interior surfaces of the two tabs together, with an H-shaped seal. While this seal is being formed, the heat simultaneously "sterilizes" the exterior melting surfaces and cuts a channel between the two tabs which allows subsequent fluid flow between them (Fig. 2).

A previous prototype round-AFTS was extensively tested for sterility and mechanical strength in 1975 (1). While the round AFTS was found acceptable in these tests, the flat form was developed for easier use and more positive sealing (2). Limited mechanical and sterility testing has been done with the flat AFTS used as part of a blood-freezing plastic bag system (3,4).

In this report we tested the sterility of the flat AFTS when the seal tabs were contaminated purposely with bacteria before sealing. The results of these studies may support subsequent development of the docks as part of a blood bag system.

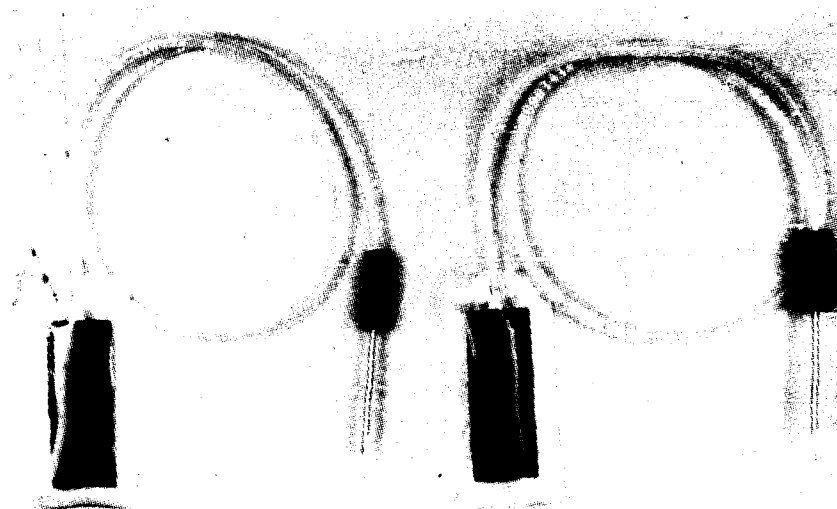


Figure 1. A pair of AFTS, showing the docking tab at the left end and the 20-gauge needle on the other (right) end.



Figure 2. Two pairs of docking devices. The top pair of tabs shown before docking, and the bottom pair after sealing and docking. The bottom pair shows the H-shaped channel cut during the sealing process.

METHODS

About 100 pairs of the flat AFTS were made for us by JPL. These units consist of polyether sulfone tabs attached to 12-inch lengths of PVC tubing, to which was attached a 20-gauge needle. We borrowed from JPL the radiofrequency sealer used to connect the tabs.

The AFTS were sterilized by either standard steam or gas autoclaving techniques. Each was wrapped in a Tower Dual Peel^R, Evanston, IL, sterilization pouch. Half of the tabs were attached to empty sterile B-D Vacutainer^R, Rutherford, NJ, tubes via the 20-gauge needle. An equal number of tabs were similarly attached to sterile tubes of Becton Dickenson supplemented peptone broth. A 25 ul aliquot of Bacillus stearothermophilus spores (1×10^4) were applied to the center of an "empty tube" tab and overlaid with a "peptone broth" tab. The two tabs were squeezed together to form a wet film between them and sealed with the RF sealer. After sealing, about half of the peptone broth was passed over to the empty Vacutainer via the connected tabs. The broth tube was vented to facilitate transfer, the docks were removed, and both tubes were incubated at 37 C for one week. Each docking site was checked for mechanical soundness and leakage during the fluid transfer step. All culture results were recorded as positive or negative, with the positive cultures being gram stained and characterized to insure that the growth was Bacillus stearothermophilus.

RESULTS AND DISCUSSION

The study was done in three runs, each on a different day. The overall results are presented in Table.

TABLE
Summary of Sterile Docking Experiments

Run	MECHANICAL FAILURES			STRUCTURALLY SUCCESSFUL DOCKS *	
	Total No.	No. Channel	End Split	Total No.	Sterile
1	19	2	8	8	7
2	16	4	0	12	11
3	24	0	0	24	23
Totals	59	6	9	44	41

* Sterility data presented only on those docks which were structurally successful.
Three docks were discarded (two on day 1) because of obvious operator error.

The first run was done with tabs which had been steam sterilized. Of the 19 docks which were attempted without obvious operator error, 11 failed due to mechanical problems. In two cases the tabs sealed but did not form an open channel between them. In nine more cases, successful mechanical seals were made but when the fluid was transferred, it leaked out the end of one of the docking tabs. Fluid transfer from the peptone broth tube to the empty tube required that the broth tube be vented to avoid formation of a vacuum. To get half of the broth into the "empty" tube also usually required application of a slight positive air pressure on the vent, via a 50-cc syringe. The pressure used was not excessive and was similar in magnitude so that created by a blood bag plasma expressor. This mild pressure may have induced leaks at sites in the tabs which has been weakened by the steam sterilization process. Several pairs of non-sterilized tabs were subjected to the docking procedure to check their mechanical strength. None leaked, and a decision was made to sterilize the remaining tabs by a gas technique. Of the eight mechanically successful docks in the first run, one developed bacterial growth in the fluid-receiving tube only.

In the second run the leakage problem appeared to have been corrected by switching to gas sterilization. However, of the 16 docks attempted, four failed because no channel was formed between the sealed tabs. This occurred on the 2nd, 9th, 10th, and 12th attempts. Of the 12 successful docks, one developed growth in the receiving tube only. This occurred on dock No. 11 which may indicate an undetected mechanical problem in the seal due to temporary variation in the performance of the RF sealer between docks No. 9 and 12.

The third run consisted of 24 docks with no detected mechanical failures. Of these, one fluid-receiving tube developed bacterial growth. One of the vented peptone starting-tubes in this series developed growth, but the corresponding receiving tube was negative.

The overall results of this study produced 44 docks that appeared mechanically successful, of which 41 remained sterile, to yield a 93% success rate. A higher rate will be needed to have a clinically acceptable product. This may be easy to achieve by minor modifications of the current prototypes. Supplying the tabs with a sterile peel-off covering would also be valuable.

The mechanical problems of the current tab and RF sealer prototypes need to be addressed before serious IND-related testing can be done. These problems fall into three main areas. First, the industry-wide accepted method of sterilizing blood bags and other biomedical plastics is by steam autoclaving. If these tabs are to be conveniently incorporated into plastic bag systems, they should

be autoclavable. This could be achieved by minor changes in the sealed edges of the tabs. The second problem is the failure of 10 percent of the docks to cut a channel between the two tabs during the sealing process. The designers of the RF sealer feel that this problem will be easy to solve. We suggest some modifications of the sealer that may help assure correct operator usage. These include a "Ready" light to indicate that the unit is ready to make the next seal, a ratchet-controlled hand held device to apply the pressure needed during sealing, and perhaps a larger sealer-head area. The third mechanical problem is the need to human engineer the sealer head for greater safety and fail-safe alignment. The model we used had an open head with the trigger switch located in close proximity. One worker received a bad burn when the RF energy shorted from the head (containing a pair of tabs) to the operators finger which was depressing the trigger switch. In addition, the sealer head and the tabs need to be configured to insure that the tabs can be inserted only in the "correct" manner and with good alignment.

The overall concept of sterile docking (or sterile splicing) is needed if the biomedical plastics technology is to support new developments in medical treatment and the field/home adaptability of these advances. Sterile docking would have a significant impact on the flexibility of manipulating frozen blood products, on salvaging stored blood, and on introducing additives to blood products. Sterile docking would also allow for on-site (in the field) filling of plastic bags with USP water also made on site. These bags could contain freeze dried hemoglobin, dry saline, or other dried resuscitation formulations. This would reduce the instability problems of these products, and reduce shipping weights and volumes of the products up to 80 percent. Sterile docking would also allow greater flexibility in the home treatment of renal dialysis patients.

CONCLUSION

With all of these potential applications, it is apparent that the time has come to develop a reliable sterile docking device. The current JPL prototypes are a definite step in this direction and, with some modifications, should be subjected to further testing with the goal of FDA listing as an approved medical device.

RECOMMENDATION

None

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