



PROFESSIONAL INFORMATION REPORT **83-1**

MAINTENANCE OF STERILITY IN
CHEX-ALL® STERILIZATION PACKAGING

Maintenance of Sterility in CHEX-ALL® Sterilization Packaging Products: Two-Year Study

SUMMARY:

A series of joint tests were conducted by Proper Manufacturing Co., Inc. and American Biological Control Laboratories, Inc. to determine how long items remained sterile once they were sterilized inside CHEX-ALL® sterilization packaging products.

Shelf-life tests were carried out for a period of two years. The results for the two-year period show no recontamination.

PROTOCOL:

One hundred disassembled 10-ml glass syringes were placed inside CHEX-ALL® pouches, one per pouch. The pouches were heat sealed by two parallel seals each ¼ inch wide.

The pouches were sterilized in a pre-vacuum steam autoclave at 272°F (133°C) for 5 minutes. It was observed that after this cycle, the preprinted chemical indicators turned to their end-point colors on both the inside and the outside of each pouch.

Pouches were randomly selected for initial sterility testing at American Biological Laboratories. Each pouch was opened in a laminar flow hood and the plunger and barrel separately transferred aseptically into culture broths. An equal number of samples were cultured in soybean casein digest and in fluid thioglycolate broths.

The remaining pouches were placed on open shelves in Proper's laboratory. To maximize the challenge, the pouches were placed in an area just under the exhaust of an air conditioning port. The packages were redistributed on the shelves every two weeks to simulate handling and to avoid the possibility of a given pouch resting-within an accidental air pocket.

After time periods of one, two, three, six, nine, twelve, eighteen and twenty-four months, the contents of ten randomly selected pouches were cultured in a manner similar to the initial sterility test.

Results:

	Soybean-Casein Digest No. Recontaminated/ No. Tested	Fluid Thioglycollate Medium No. Recontaminated/ No. Tested
Initial Sterility	0/19	0/19
1 Month	0/10	0/10
2 Months	0/10	0/10
3 Months	0/10	0/10
6 Months	0/10	0/10
9 Months	0/10	0/10
12 Months	0/10	0/10
18 Months	0/10	0/10
24 Months	0/10	0/10



DISCUSSION:

Testing of CHEX-ALL® packaging products has demonstrated that, for a time period of TWO YEARS, they are capable of maintaining sterility of items sterilized within. This time period is considerably in excess of expected storage times of hospital sterilized items.

While there are no recognized standard conditions for shelf-life testing of sterile packages, efforts were made in these tests to expose the sterilized pouches to particularly adverse but realistic conditions, such as open shelving and frequent handling.

These tests were performed to provide information on the self-life capabilities of CHEX-ALL® packaging. Each institution must use caution in extrapolating these data to their individual storage and handling conditions. Various local or state health agencies may also regulate the permissible shelf-life of sterilized packages.

