



PROFESSIONAL INFORMATION REPORT **81-2**

MAINTENANCE OF STERILITY IN
CHEX-ALL® II STERILIZATION POUCHES
(Supersedes Professional Information Report 81-1)

SHELF LIFE RECOMMENDATIONS:

Propper Manufacturing Company's series of tests demonstrate that the Chex-All® II Self-Sealing Sterilization Packaging System retained its microbial barrier properties for a time period of at least two years. This is considerably in excess of current practice standards for the storage times of sterilization pouches (heat sealed or "self-sealed").

While there are no national standards for the shelf life of sterilized packages, published information indicates a consensus procedure of:

"Six months to one year"¹

"Or at least one year"²

It should be understood that although attempts have been made to maximize the microbial challenge, it is not possible to predict every type of contamination challenge that might occur during regular use of these products.

It must be recognized, of course, that sterility maintenance by any type of package is related to what happens to that package during storage, rather than to the length of its storage time. Mrs. Peggy Ryan, an eminent nurse consultant¹, stated: "Faulty packaging and careless handling, as well as improper storage conditions, cannot be made safe by an expiration date or re-sterilization of items within any given time limit."

Sound principles of material management must also be considered when the shelf life of each sterilized medical product is established.

Maintenance of Sterility in CHEX-ALL® II Sterilization Pouches: Two-Year Study

SUMMARY:

Sealed Chex-All® II sterilization pouches containing gauze pads were sterilized by saturated steam. After sterilization, these pouches were stored in a location that was conducive to recontamination of the pouches. At periodic storage intervals, randomly sampled pouches were aseptically opened and the gauze pads cultured for the isolation of any microbial contaminants. After twenty-four months of storage, Chex-All® II pouches still maintained sterility as evidenced by the lack of microbial isolates from pouch contents.

1. Ryan, R.N.: Inhospital Packaging Rationale; AORN Journal, May 1976, Vol. 23, No. 6, p.986.

2. U.S. Dept. Health & Human Services, Centers for Disease Control: Guidelines for Prevention & Control of Nosocomial Infections, B.P. Simons, M.D., Guidelines for Environmental Control: Disinfection & Sterilization, October, 1981, page 6.



METHODOLOGY:

One hundred and forty sealed Chex-All® II pouches were prepared by inserting a 4 x 4 inch gauze pad into each pouch and then sealing the pouch in accordance with printed instructions. The pouches were sterilized by a pre-vacuum saturated steam cycle of four minutes at 272° F (134° C). Steam was chosen as the test sterilant since it is more damaging to packaging than is ethylene oxide gas. A pre-vacuum type of cycle was employed because it produces the greatest stress to the material and the seal integrity of a pouch.

In order to maximize the risk of microbial recontamination of the sterile pouch contents, sterilized pouches were stored under a duct of the laboratory air-conditioning system. These pouches were randomly rearranged every two weeks to equalize their chances for recontamination and to simulate their being handled during their shelf life.

After each storage period of one, three, six, nine, twelve, eighteen and twenty-four months, the gauze pads inside random samples of pouches were aseptically removed and cultured in both tryptic soy broth and in thioglycolate broth.

RESULTS AND DISCUSSION:

Recontamination of sterilized pouches can be determined by the isolation of any microbial flora from the contents of a previously sterilized pouch. Table 1 presents data on the number of pouches re-contaminated after storage periods of up to twenty-four months.

Table 1. Recontamination of Sterile Chex-All® II pouches after various storage periods (a).

Storage Period	Steam Sterilized TSB (b)	Pouches TB (c)
1 mo.	0/20	0/20
3 mo.	0/10	0/10
6 mo.	0/10	0/10
9 mo.	0/10	0/10
18 mo.	0/10	0/10
24 mo.	0/10	0/10

(a) Expressed as a number of pouches found recontaminated/ number tested

(b) tryptic soy broth

(c) thioglycollate broth

The results show that Chex-All® II sterilization pouches were able to maintain sterility of their contents for up to two years after steam sterilization. (Various local or state health agencies may limit the permissible shelf life of sterilized packages.)





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DATE: Dec. 16, 1981

SUBMITTED TO: Proper Manufacturing Co., Inc.
Long Island City, N.Y.

ASSAY NUMBER: 21160

DATE RECEIVED: Nov. 25, 1981

TEST MATERIAL: 20 pouches Chex All II containing gauze pads,
sterilized at Proper on 11/26/79 at steam 272°F
for 4 min. Pouches stored on open shelving.

METHOD OF ASSAY: U.S.P. XX

RESULTS:

	Number Sterile	Soybean Casein
Fluid Thioglycollate	10	10

The test material and sporestrips, as submitted, are sterile.

IL:gm

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While there are no recognized standard conditions for the testing of shelflife of sterilized packages, the experimental design was such that it would simulate realistic, albeit somewhat harsh conditions of storage and handling frequency. Caution is expressed about directly extrapolating these data to all storage conditions.