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# IMPRESSION MATERIAL STERILIZATION WITH GASEOUS ETHYLENE OXIDE

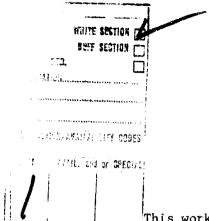
by

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# ADMINISTRATIVE INFORMATION

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# ABSIRACT

The increase in surgical treatment of oral, facial, and cranial defects has prompted a concemitant increase in requests for impressions to be made in the singleal theater. To avoid violation of the sterile chain, impression materials and equipment should be sterile. Irreversible hydrocolloid and plaster materials are practical for use in the operating room but cannot be sterilized by autoclaving and other high temperature methods; and whother they are sterile as received from the manufacturer is questionable. The purpose of this study was to determine the effectiveness of gascous ethylene oxide treatment in sterilizing hydrocolloid powder and fast setting plaster; and to determine the effect of the prosudure on the physical properties of the hydrocolloid. Spores of Bacillus subtilis var. globigii were mixed with the respective materials to yield a spore concentration of about 1.0 x 10<sup>8</sup> colony-forming units per gram of pewder. Symples of 20 to 40 grams of pewder in envelopes were subjected for 48 minutes to ethylene exide gas in a 1-cubic-foot capacity Steri-Vac onit. After 48 hours of airing, the samples were assayed for microorganisms, and softing time and duplicating properties of the material were tested No bacteria were recovered from the 30 samples of each type of material exposed to ethylene oxide gas, but they were recovered from control samples not exposed to the gas, agoth materials were found to be contaminated with gram-positive bacilli and coccl as received from the manufacturer. There was no significant difference between setting times and linear measurements of sterilized and nensterilized samples.

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# INTRODUCTION

The increase in surgical treatment of oral, facial, and cranial defects has prompted a concomitant increase in requests for impressions to be made in the surgical theater. To avoid violation of the sterile chain, sterile impression materials and equipment should be used.

Irreversible hydrocolloid is one of the most practical impression naterials for use in the operating room. The equipment (mixing bowl, spatula, and measuring devices) is simple and easily sterilized, and no electricity or open fiame is required. Trays to contain the material can be constructed in any size or shape with acrylic resing or the hydrocolloid can be backed and supported with fast-setting plaster. Although some decrease in dimensional accuracy may result, alginate's flow properties and setting time can be inveniently altered by changing the water-powder ratio and the water temperature. Maraheri and Sahni<sup>1</sup> have described manipulation of the material in fabrication of serial diagnostic casts and moulages for cleft palate patients. Both irreversible hydrocolloid<sup>2</sup> and plaster detericrate rapidly at elevated temperatures and in the presence of moisture, so they cannot be sterilized by autoclaving and other high temperature methods. A practical means of sterilizing these materials is needed since it is questionable whether they are sterile as received from the manufacturer.

Gaseous ethylene oxide is an effective sterilizing agent at temperatures considerably lower than those attained in an autoclave or in a dry-heat sterilizer. For this reason, it is used to sterilize materials easily destrived by high temperatures.<sup>3</sup> The purpose of this study was no determine the effectiveness of gaseous ethylene oxide treatment in sterilizing bydric likid powder and fast-setting plaster; and to determine the effect of the procedure on the physical properties of the bydric likid material

# MATERIALS AND METHODS

Tests for the effectiveness of sterilization procedures were made using the resistant spores of <u>Bacilius subtilis</u> var. <u>Blobigin</u>. The spores were mixed with type II normal-setting inteversible hydrocolloid powder<sup>\*</sup> and a fast-setting plaster material to yield a concentration of about  $1.0 \times 10^8$  colored rming only per gram of pewder. Artifically contamimated aliquots of 10 to 30 grams (three units with the manufacturer's measure) of hydrocolloid powder and 30 to 40 grams (two units with the lanufacturer's measure) of plaster materials were transferred to paper sterilizing envelopes. A total of 30 envelopes for each type of material

The opinions of Assertions contained herein are the private ones of the writers and are not to be construed as official or as reflecting the views of the Navy Department or the naval service at large.

\*Caulk, Jeitrate, Alginate Impression Material, L. D. Caulk Co., Milford, Dei.

Kerr Manufacturing Co., Detroit, Mich.

Mamerican Hospital Supply Corp., Cat. No., 6530-754-0421. Edison, N.J.

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were exposed, in six separate trials, to gaseous ethylene oxide<sup>\*</sup> for 48 minutes in a sterilizing unit<sup>†</sup> with a capacity of 1 cubic foot. The envelopes were then aired in an open area for 48 hours at room temperature for removal of residual ethylene oxide material.

The samples of hydrocolloid and plaster powders that had been exposed to ethylene oxide gas were then assayed for microbial contamination. About 1 gram of powder from each envelope was aseptically transforred to a separate tube of trypticase sey broth. Iurbidity could not be used as a criterion of bacterial growth bec use the broth-powder mixture was already turbid before incubation. Therefore, 0.1 ml amounts of the mixture were plated with trypticase suy agar  $\dagger$  pours (1) immediately, and (2) after incubation of the original mixture for 24 hours at 37° C. Contamination or pencentamination of the materials was determined by the presence or absence of colonies in the agar medium and by microscopic examination for organisms using Gram staining procedures. Thirty control samples of the actificially contaminated materials were simultaneously subjected to the same assay procedure but without previous exposure to ethylene oxide. To determine whether the hydrocolloid powder and the plaster were contaminated as received from the manufactures, samples were removed aseptically from three freshly opened packages of each type of material and assayed in the same marmer.

The effect of the sterilizing procedure on the physical properties of the irreversible hydrocolloid material was evaluated by testing for setting time and accuracy of duplication. A total of 30 samples were subjected to a test for setting time as set forth in American Dental Association specification No. 18.4 A total of 10 nonsterilized control samples were subjected to the same test for comparison. Accuracy of duplication was tested on samples from 18 envelopes filled with irreversible hydrocolloid powder previously exposed to gaseous ethylene exided the test consisted of using the material mixed from the powder to cach envelope to make an impression of an acrylic resin rectangular form utilizing a specially adapted r iforated metal tray. The impressions were proved with a standard mix of dental stone. Five additional impressions of the fectional were made from consterilized algorate and poured in the same manner. The cases were then measured lineally with a micromeasuring device?

### RESCI15

raterial growth was not observed in any of the artificially contaminated hydrocoli idor plaster samples exposed to gaseous ethylene exide that the work posel samples were all contaminated with the test

Sterr-Gas Cartridge (one cartridge per run contained 30 grams of FOX ethylore oxide material)

<sup>†</sup>Steri-Vac Sterilize: Mcdel H100 - 3M Col, St. Paul, Minn. <sup>†</sup>haltimore Biological Laboratories - Baltimore, Md. <sup>5</sup>Central Scientific Col. Newark, N.J. bacterium. The samples of hydrocolloid and plaster as received from the manufacturer were all found to be contaminated with gram-positive bacilli and cocci.

The effect of gaseous ethylene oxide sterilizing procedures on the physical properties of hydrocolloid material is shown in table 1. There was no significant difference in setting time and linear measurement between the materials mixed from the sterilized and nonsterilized powder samples.

	Setting time (min)	Linear measurement of casts (mm)		
Control (nonsterilized)	$3.5 \pm 0.1 (10)^*$	54.92 ± 0.03 (5)*		
Experimental (sterilized)	3.5 ± 0.1 (30)*	54.93 ± 0.04 (18)*		

Table 1.--Effect of gaseous ethylene oxide sterilizing procedures on physical properties of irreversible hydrocolloid

"No. of powder samples

# DISCUSSIO

It is not known whether the contamination present in the hydrocolloid and plaster proder as they are received from the manufacturer represents a potential health hazard in routine clinical use. Procedures involving surgery, however, demand the use of sterile impression materials. In this respect, ethylene exide was shown to be very effective. Although gaseous ethylene oxide is widely used to sterilize many materials, its use for sterilizing hydrocolloid powder has not previously been reported. Gaseous ethylene oxide as a sterilizing agent is known to have excellent penetrating properties, and it leaves no residual chemical when materials are aired for adequate periods.<sup>3</sup> The packaging of powder in small amounts. e.g. three measures, provides convenient quantities for practical use and at the same time provides a small bulk for maximum penetration of the gaseous agent. The foregoing results indicate that the ethylene wide procedure is effective in sterilizing hydrocolloid and plaster materials even when they contain resistant spores. Furthermore the sterilization procedure does not adversely affect the setting time and linear dimensions of the hydrocolloid material.

The sterilization method used in this study showed itself to be effective and practical. The making of impressions of surgical defects under sterile conditions---for procedures such as cranioplasty

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tympanoplasty, and oculoplasty--now seems feasible. The fabrication of therapeutic contact lenses, skin graft splints, and neonatal cleft palate prostheses are other procedures that warrant the use of sterile impression materials.

# SUMMARY

In this study, 30 samples of one type of irreversible hydrocolloid powder and 30 samples of one type of plaster material were sterilized using gaseous ethylene oxide. The procedure did not adversely affect the setting time or the dimensional accuracy of the hydrocolloid material.

# ACKNOWLEDGMENTS

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Security Classification 14 KEY WORDS		IK A	LINK B ROLE WT		LIN ROLE	KC WT
Contamination	ROLE		ROLL		HOLE	
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Ethylene oxide gas Impression materials						
Sterilization						
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