

## A Potential Hazard Connected with the Resterilization and Reuse of Disposable Equipment

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"Disposable" anesthetic equipment is often cleaned and reused in the name of economy and/or convenience.<sup>1</sup> The following report illustrates a hazard of this practice.

### REPORT OF A CASE

A 48-year-old man underwent an uneventful thoracotomy for left stellate ganglionectomy with use of general anesthesia. At the completion of the operation the oral thermometer probe and the esophageal stethoscope§ (24-French, clear plastic, disposable) were removed. During removal, slightly more than the expected resistance was encountered. The patient's oropharynx was suctioned, his trachea was extubated, and he was taken to the recovery room. Upon his arrival in the recovery room, the oral airway was removed, after which the translucent balloon from the tube portion of the esophageal stethoscope was discovered (fig. 1). It was recovered intact. There was no evidence that aspiration had occurred.

### DISCUSSION

The broken esophageal stethoscope described above was manufactured as disposable. For economy, because these devices appear to be substantial, our hospital has cleaned and resterilized (ethylene oxide) them for reuse.

The Medical Devices Act of 1976 empowers the Food and Drug Administration (FDA) to issue policy guidelines for medical devices. One of these guidelines deals with the reuse of disposable medical devices.<sup>2</sup> It states in part that "the institution or practitioner who reuses a disposable medical device should be able to demonstrate: 1) that the device can be ade-

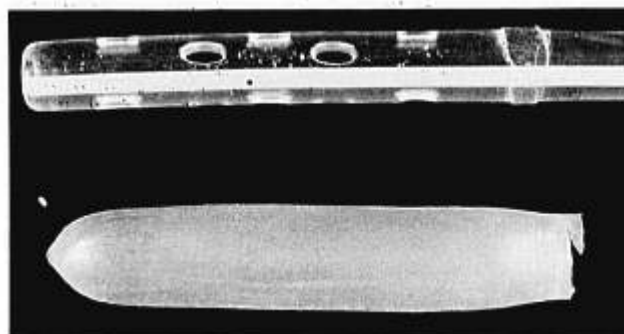


FIG. 1. Fragmented esophageal stethoscope and balloon diaphragm fragment.

quately cleaned and sterilized; 2) that the physical characteristics or quality of the device will not be adversely affected; 3) that the device remains safe and effective for its intended use. Moreover, since disposable devices are not intended by the manufacturer or distributor for reuse, any institution or practitioner who resterilizes and/or reuses a disposable medical device must bear full responsibility for its safety and effectiveness." Consultation with the manufacturer reveals a possibility that repeated exposure to ethylene oxide and heat may leach out plasticizers and weaken the structural integrity of polyvinylchloride.<sup>3</sup>

We believe that two points are illustrated by this report. First, fragmentation of disposable esophageal stethoscopes may occur, causing potential airway hazard. Second, by federal statute, one may assume liability when resterilizing and reusing a disposable medical device.

### REFERENCES

1. Stetson JB, Whitbourne JE, Eastman C: Ethylene oxide degassing of rubber and plastic materials. *ANESTHESIOLOGY* 44:174-180, 1976
2. Chapter 24, Devices, Food and Drug Administration Compliance Policy Guidelines, EDRO, Division of Field Operations, Guide 7124.23, 11 November 77, pp 1-2
3. Emerson J, American Hospital Supply, Santa Ana, California: personal communication

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