

# CORRESPONDENCE

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## Propofol: Can a Single Ampule Be Used for Multiple Patients?

*To the Editor:*—The Center for Disease Control's Center for Infectious Disease in May through June 1990 received reports of four post-surgical infections and/or hyperthermic reactions that developed in patients after a variety of surgical procedures. The reports were directed from four different states and have been associated with three different pathogens.<sup>1</sup>

All patients received propofol (Diprivan®), and there is some belief that the same syringe may have been used on different patients. The preliminary results of these investigations suggest that contamination of propofol was extrinsic (contaminated during the manipulation after receipt from the manufacture).

We have performed the following study to determine if propofol would incur bacterial growth if aseptically aspirated and left at room temperature. Ten ampules of propofol were opened under standard aseptic technique. Ten milliliters of solution was withdrawn from each ampule. Then, in ten separate syringes, 5 ml was aspirated. These 5-ml aliquots were labeled and immediately sent to the laboratory. Each aliquot was cultured at 2, 4, 6, 8, and 12 h after the original collection. All specimens were independently cultured on 5% sheep agar for 72 h. There was no growth in any of the samples at the end of the 72 h. The specimens then were subcultured onto trypticase medium and showed no growth within an additional 72 h.

This study shows that if propofol is aspirated into sterile unit dose

syringes using standard accepted techniques, it can be bacterial-free for 72 h. In theory, propofol can be used for up to 72 h after opening the ampule. However, in clinical practice, no medication such as this should be left open for this period of time. A single ampule of propofol could be used on multiple patients if aspirated aseptically into separate syringes immediately upon opening of the ampule.

GREGORY J. DOWNS, M.D.  
*Chief, Anesthesia*

PETER R. HALEY, C.R.N.A.  
JAIME B. PARENT, M.S., M.T. (A.S.C.P.)

*General Delivery*  
*Box 2500*  
*March Air Force Base, California 92518*

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*In Reply:*—Downs *et al.*'s data support evidence in the literature that the use of standard aseptic technique minimizes the potential for any extrinsic contamination through inappropriate handling. In contrast to Downs *et al.*'s conclusion that propofol (Diprivan®) could be used on multiple patients from a single ampule, the Diprivan® label specifically indicates that Diprivan® should be prepared for single-patient use only and just prior to the initiation of each individual procedure.

ICI Pharmaceuticals Group's Research and Development recently conducted a study to determine the potential for microbial contamination of Diprivan® using a specific handling technique.\* Using this technique, Diprivan® was transferred from 140 vials into sterile syringes. Multiple samples were taken from each syringe over a 12-h test period using a randomized incomplete block design. Samples were tested mi-

crobiologically using bacterial filtration with both broth and agar media to maximize the detection of microorganisms.

As indicated in table 1, of the 2,040 test samples from syringes, only two (0.098%) tested positive for microorganisms. These two samples were from different syringes; one sample tested positive at 6 h and the other at 8 h. Testing of samples from these two syringes at all other test periods, including the 12-h time point, showed no contamination. The very low levels of contamination observed in these two samples are consistent with the background contamination inherent in the procedure used to test the samples.<sup>1</sup> It is not consistent with contamination of the Diprivan® during aspiration into syringes.

In response to reports of cases of postoperative infection where breaks in aseptic technique may have led to extrinsic contamination of Diprivan®, the company has, in conjunction with the Food and Drug

\* Diprivan® handling technique specified in study:

1. Wear clean surgical scrubs.
2. Wash hands and fingernails using antimicrobial handwash.
3. Remove metal cap from vial.
4. Disinfect rubber stopper of vial using 70% isopropyl alcohol.
5. Insert vent spike through rubber stopper and remove Luer cap.
6. Connect sterile syringe(s) and withdraw entire content.
7. Immediately cap each syringe with sterile closure.
8. Discard vial and vent spike.
9. Label syringe with appropriate information.
10. Take labeled syringes to laboratory for testing.

TABLE 1. Susceptibility of Bacterial Growth in Propofol as a Function of Time

Time (h)	Thioglycollate Broth (Filter)	Chocolate Agar (Filter)	Spread Plate Technique
Zero	0/180	0/180	
4	0/180	0/180	0/60
6	1/180	0/180	0/60
8	1/180	0/180	0/60
12	0/180	0/180	0/60

Data are positive test samples/total test samples.

Administration (FDA), further revised the label and package insert for Diprivan®. The new labeling and package insert instructions for Diprivan®, as summarized below, further emphasize the importance of adherence to strict aseptic techniques:

- Prepare just prior to each procedure
- Withdraw contents immediately after opening
- Administer promptly
- Complete administration in 6 h

The 6-h time limit for use after opening an ampule or vial was established in close consultation with the FDA. This time limit was selected to reinforce the importance of using safe handling procedures in the preparation and administration of Diprivan®.

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DAVID B. GOODALE, D.D.S., PH.D.  
*Associate Director, CNS and Anesthesia  
Stuart Pharmaceuticals  
ICI Pharmaceuticals Group  
Wilmington, Delaware 19897*

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## A Modification of the Laryngeal Mask Airway

*To the Editor:*—We agree with Grebenik *et al.*<sup>1</sup> that the laryngeal mask airway (LMA) offers particular advantages over traditional techniques for providing general anesthesia to children receiving radiotherapy. We report a potential problem and our solution.

We were recently asked to provide anesthesia for a 3-yr-old boy undergoing a course of radiotherapy for a rhabdomyosarcoma. The patient was to be prone, as the treatment involved the spine as well as the head, which was to be held firmly in a plastic mold. There was no evidence of cerebral edema or raised intracranial pressure. As we were anxious to avoid frequent tracheal intubation, the laryngeal mask was considered. At the planning session, a size-2 LMA was inserted under inhalational anesthesia, allowing spontaneous ventilation *via* a clear airway. However, after turning to the prone position, there was marked clinical evidence of partial airway obstruction, including intercostal and suprasternal recession, paradoxical respiration, and stridor. Although hemoglobin saturation remained above 96%, an unacceptable end-tidal carbon dioxide (ET<sub>CO<sub>2</sub></sub>) of 9% was recorded. A lateral radio-

graph, taken to plan therapy, revealed a sharp kink in the tube of the LMA.

A size-2 LMA was reinforced internally with a shortened plain 5.5-mm Mallinckrodt armored tracheal tube and was used on the next occasion. The clinical signs of airway obstruction described above were no longer present, and ET<sub>CO<sub>2</sub></sub> was recorded at 6-6.5%. This modification allowed us to avoid repeated tracheal intubation. Figure 1 illustrates that kinking is prevented in the modified LMA.

We understand that the manufacturers are to strengthen the size-2 LMA to avoid the problem of kinking, although it is difficult to imagine that anything other than wire reinforcement would have prevented kinking in the position our patient was required to adopt.

I. G. WILSON,\* F.F.A.R.C.S.  
*Lecturer*

R. EASTLEY, F.F.A.R.C.S.  
*Consultant*

*University Department of Anaesthesia  
Leicester Royal Infirmary  
Leicester LE1 5WW  
United Kingdom*

*\*Current affiliation:  
Visiting Assistant Professor  
Department of Anesthesiology  
University of Oklahoma  
Oklahoma City, Oklahoma 73152*

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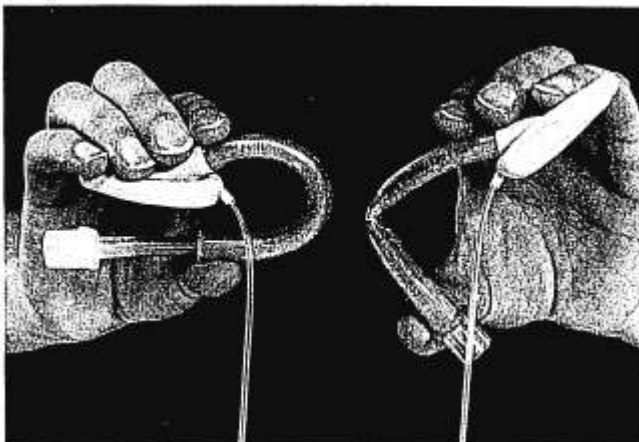


FIG. 1. Modified (left) and standard (right) LMAs.

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