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A Defect in a Self-administration Anesthesia System

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In obstetrics, self-administration of inhalation anesthetics has been successful in providing analgesia during labor and delivery. The Juno Mark 2 nitrous oxide–oxygen mixer ‡ designed for this purpose can provide, on demand, preset combinations of N_2O and O_2. Several of these machines have been used in our obstetrical unit and have been well received by both patients and delivery room personnel. Analgesia is self-administered, eliminating the problems of loss of consciousness and obtunded protective reflexes.

With increasing use of this technique, we have encountered a previously-unsuspected and potentially dangerous complication relating to the mouthpiece. The mouthpiece is basically a one-piece plastic tube, narrowed at one end to fit between the patient's lips. In appearance it resembles a whistle (fig. 1). To prevent rebreathing of expired gases, a one-way valve has been incorporated close to the patient end. The valve consists of a small plastic disk held in place by a plastic retaining ring and small plastic ribs on the inside of the tube (fig. 2).

The nurse in charge of the obstetrical unit notified us that two paients had found "little white plastic disks"" in their mouths following use of the Juno Mark 2 self-administration anesthesia machine. This was investigated.

In several of the unused mouthpieces the retaining ring was located about 2 mm distal to its normal position. In addition, some of the plastic disks were not perfectly round, being slightly smaller in one diameter than another. The internal diameter of the narrow part of the mouthpiece is only slightly smaller than the largest diameter of the disk. When the mouthpiece is warmed in the mouth and then compressed by the teeth, this inner diameter is increased slightly, and this may be sufficient to allow the disk to slip out of the mouthpiece entirely.

When the retaining ring is seated in the tube properly, the plastic disk cannot be dislodged from its point of action. However, during use, and particularly after cleaning, sterilization and reuse, the retaining ring, which is not immovably fixed in position, may shift slightly, providing enough room for the disk to find its way into the patient end of the mouthpiece and into the patient.

While the mouthpiece was originally designed to be disposable, it can be reused with proper sterilization, and the temptation to do so is difficult to resist. In many of the mouthpieces that had been used previously and then sterilized with Cidex,§ the retaining ring had migrated several centimeters and the plastic disk had migrated proximally (figs. 3 and 4) or was missing entirely.

Since most of the patients using this device are hyperventilating, the possibility of aspirating the disk into the trachea is obvious. The risk of aspiration may be increased if airway

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‡ Juno Mark 2—Fraser Sweatman Inc., 5490 Broadway, Lancaster, N. Y. 14086.

§ Cidex–Arbrook Inc., Arlington, Texas.

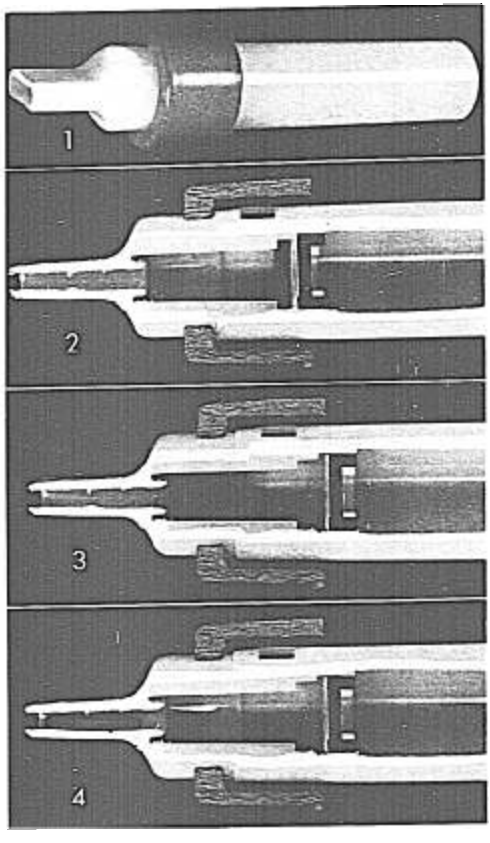

FIG. 1. The disposable nonrebreathing mouthpiece for the Juno Mark 2.

FIG. 2. Sagittal section of the mouthpiece, showing the normal positions of the retaining ring and disk. (Both have been colored for identifying purposes.)

FIG. 3. The retaining ring has slipped distally, allowing the disk to migrate towards the mouth.

FIG. 4. Further progression of the disk through the mouthpiece.

reflexes are partially obtunded by premedicants, higher concentrations of N_2O, or methoxyflurane, frequently used for self-administration techniques.

Because of the serious nature of this defect, we feel that the design of the mouthpiece should be modified to prevent the disk from being displaced in any way by making the retaining ring immovable. In addition, it should be impossible for the disk, even if displaced, to travel out of the mouthpiece into the patients mouth. This correction could perhaps be accomplished by incorporating a plastic septum in the mouthpiece proximal to the plastic disk.

We have reported these findings to the manufacturer, who has been most receptive to correcting the problem. A product recall has been issued, and corrective measures are being taken. However, we feel that all anesthesia and delivery room personnel who may have occasion to use this apparatus should be aware of this unexpected and potentially serious complication.