

CORRESPONDENCE

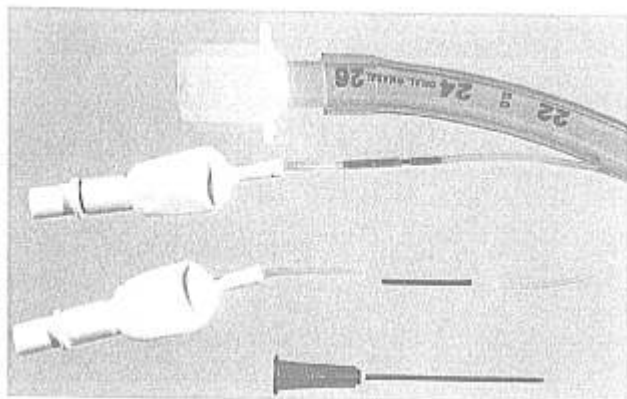


Fig. 1. (Bottom) The needle used to form the joint before it has been bent and broken into the section shown in the *middle* with the two pieces of inflation tubing to be joined. **(Top)** The assembled repair.

similar length of intact inflation tube, pilot balloon, and one-way valve from an unused endotracheal tube. Be sure to use a tube that is the same size and from the same manufacturer as the defective tube. Connect the intact one-way valve, pilot balloon, and inflation tube to the remaining section of inflation tube on the patient's endotracheal tube using a 0.5–1-inch section of a standard hypodermic

needle. This will provide a secure air-tight fit that will last for days. Use another section of inflation tube to determine which gauge needle provides the best fit. Figure 1 shows the pieces separate and assembled. A piece of tape across the joint may provide extra security; however, in our tests, we were able to inflate endotracheal tube cuffs to bursting before the needle joint failed.

There is a trick to obtaining a short section of the needle so that the ends are not sharp, deformed, or crimped closed. Using two hemostats, bend the needle back and forth, never exceeding a 30° bend, until it breaks. Repeat this to obtain a section of the needle of the desired length.

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Tec 6 Recall

To the Editor:—Ohmeda would like to inform your readers of a medical device recall initiated on July 8, 1994, involving a certain group of Ohmeda Tec 6 (desflurane) Vaporizers. Letters detailing this action were sent to users of the affected Ohmeda Tec 6 Vaporizers and Ohmeda Tec 6 NAD Variant Vaporizers. This field action addresses two conditions.

Regarding the Ohmeda Tec 6 (desflurane) Vaporizer (serial numbers ACTV32001 to ACTV51502 and serial numbers ACTW01001–ACTW30093) for use with Ohmeda Anesthesia Systems and Ohmeda Tec 6 NAD Variant Vaporizer (serial numbers ACWW14001–ACWW30288) for use with North American Drager Anesthesia Systems, Ohmeda has received a limited number of reports from the field and has confirmed from its own investigation that a few Ohmeda Tec 6 Vaporizers, manufactured before August 1, 1993, have delivered higher concentrations of the anesthetic agent desflurane than indicated by the vaporizer dial setting. This condition appears to be caused by the improper operation of a control valve inside the va-

pORIZER and may not be detected by the internal vaporizer alarms. In the majority of the reports, it was noted that the higher agent concentrations were detected with the use of an anesthetic agent monitor capable of measuring desflurane. In other instances, it was reported that the bobbins in the flowmeters of the anesthesia system were noted to jump frequently.

Investigation to date by Ohmeda of the vaporizers identified in the reports has indicated the condition occurs at high flow rates and concentrations. Therefore, to help avoid the potential for high output, Ohmeda recommends a maximum vaporizer dial concentration of 6% at a flow rate of 4 l/min. At flow rates of 3 l/min or less, the concentration may be increased to a maximum of 9%. Concentrations above these limits should not be used as the investigation of some user reports have identified delivered nominal concentrations of 17–20% at a dial setting of 12% and flow rate of 5 l/min. At full scale, which is 18%, and with a flow rate of 5 l/min, concentrations in the nominal range of 21–25% have been seen. If it is suspected that,

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during use, the vaporizer is delivering higher concentrations of the anesthetic agent desflurane than indicated by the vaporizer dial setting, turn the Tec 6 OFF.

The operation and maintenance manual for the Ohmeda Tec 6 Vaporizer contains precautions warning against filling the vaporizer with any substance other than desflurane. During use of the Tec 6, ensure that external contaminants, such as cleaning agents and lubricants, are not used on the vaporizer or the filling port on the bottle of the anesthetic agent.

Regarding the Ohmeda Tec 6 NAD Variant Vaporizer (serial numbers ACWW14001–ACWW51200 and serial numbers ACWX01001–ACWX19010) for use with North American Drager Anesthesia Systems, Ohmeda has received a limited number of reports stating that the adapter manifold required for use of the Tec 6 NAD Variant Vaporizer has developed a significant fresh gas leak when the vaporizer was turned OFF after use, such as at the end of a case. This condition is caused by a manifold valve being held in an open position. The internal plunger of this valve can become lodged against the flow control holes of the valve body, creating a passageway for a gas leak. It can be detected by the pressure, volume, and/or carbon dioxide monitors of the anesthesia system. A leaking sound, such as a hissing noise, also may be present.

If the condition occurs during use, the following steps should be taken:

If the Tec 6 "No Output" alarm is not activated:

- Fully depress and release the Dial Release Button.
- If the leak continues, temporarily ventilate the lungs manually using oxygen flush to maintain patient gas supply.
- Discontinue case or use an alternative anesthesia system, as appropriate, with a resuscitator to maintain patient ventilation.

If the Tec 6 "No Output" alarm is activated:

- Decrease fresh gas flow to 3 l/min or less.
- If alarm clears, fully depress and release the Dial Release Button.
- If alarm or leak continues, temporarily ventilate the lungs manually using oxygen flush to maintain patient gas supply.

- Discontinue case or swap anesthesia system, as appropriate, using a resuscitator to maintain patient ventilation.

Reports received to date have not involved patient injury for either condition. However, without timely recognition, the patient's condition could deteriorate to a point where, without intervention by a trained medical professional, serious injury or death may result.

All users of the Tec 6 must be made aware of this notice and may continue to use the Tec 6 Vaporizer. As always, it is imperative that users observe patient vital signs and applicable monitor outputs. The preoperative checkout procedures described in the Ohmeda Tec 6 operation and maintenance manual and the appropriate preoperative checkout procedures for the particular North American Drager anesthesia system also must be performed before each use. Ohmeda also strongly recommends the use of an anesthetic agent monitor capable of measuring desflurane.

A service representative will be contacting facilities to schedule a visit to replace the affected Tec 6 Vaporizers with a version designed to eliminate improper operation of either valve. There will be no charge for this replacement. The Food and Drug Administration has been informed of this recall.

This letter will be published in other journals in an effort to inform as many users as possible. Questions regarding this information can be directed to Cathy Johnson at 1-800-521-0086.

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