



FDA PUBLIC HEALTH ADVISORY: OCCLUDED ENDOTRACHEAL TUBES

To: **Anesthesia Care Providers
Emergency Care Providers
Respiratory Care Providers**

February 28, 1994

This is to advise you of a potentially serious problem associated with the use of uncuffed pediatric endotracheal tubes.

FDA has received several reports of a colorless material inside endotracheal tubes which occludes the lumen and prevents adequate ventilation of the patient. The material causing the obstruction is not easily detected by visual inspection. It can remain undetected until after the child is intubated, thereby necessitating reintubation, and potentiating a life-threatening, emergency situation.

We recommend the following precautions when using pediatric endotracheal tubes:

- Check the patency of all endotracheal tubes (tube and connector) immediately prior to intubation.
- Do not allow solutions/lubricants that can form film barriers to enter the lumen of the tube.
- If it becomes necessary to reconnect the endotracheal tube and the connector, do not use solutions/lubricants that can form film barriers.
- In particular, do not use cellulose products (e.g., lidocaine jelly) as a lubricant in reconnecting endotracheal tubes and connectors, and keep this material out of the lumen of the tube. FDA laboratory analysis has determined that 2% lidocaine jelly can form a film inside a 5 mm connector that could, after sufficient "curing time," become a flexible obstruction that totally occludes the lumen of these devices.

If you find an obstructed endotracheal tube, please do not discard it. Contact Judy Kalson, FDA, Center for Devices and Radiological Health, Office of Science and Technology at 301-443-2444.

If you have questions regarding this Advisory, please contact Sherry Purvis-Wynn, R.N., FDA, HFZ-510, 1390 Piccard Drive, Rockville, MD 20850, or FAX 301-594-2968.

Please remember that the Safe Medical Devices Act of 1990 requires hospitals and other user facilities to report deaths, serious illnesses and injuries associated with the use of medical devices. You may report such incidents by phoning 301-427-7500, by FAXing to 301-881-6670, or by writing FDA, CDRH, MDR User Reporting, P.O. Box 3002, Rockville, MD 20847-3002.

Sincerely yours,