September 2, 1983

FDA SAFETY ALERT:
BREATHING SYSTEMS CONNECTORS

Dear Hospital Administrator:

This is to alert you to a hazard for infants which can arise if certain incompatible "low dead space" breathing systems components are coupled together during anesthesia or respiratory therapy. The incompatibility can produce extremely high resistance to or prevent exhalation, thereby resulting in increased intrapulmonary pressure and almost certain pneumothorax.

To date, we have received one report of such an incident. To prevent further occurrences, it is important that you and your staff be aware the problem, and that you consider the preventive measures outlined below. I suggest that copies of this letter be forwarded to the following departments and/or others as appropriate:

-Anesthesiology	-Respiratory Therapy
-Nursing	-Critical Care
-Pediatrics	-Neonatology
-Emergency Medicine	-Transport Services

The problem, briefly, is as follow. Some "low dead space" breathing systems adapters incorporate a fresh gas inlet tube which may protrude into or near the end which is attached to the tracheal tube connector (the 15 mm connection area shown in Figure 1). Using these adaptors with "low dead space" tracheal tube connectors (see Figure 2) may permit the fresh gas inlet tube to closely approach or even press against the end of the connector (see Figure 3). This can cause partial or complete obstruction of the exhalation pathway, and could expose the lungs to the full inlet gas pressure.

Examples of "low dead space" adaptors with fresh gas inlet tubes which can produce this incompatibility include pediatric elbow adapters such as the Keats-Hanks-Rachow, Norman, and NRPR configurations. Anesthesia breathing circuits which incorporate a coaxial inlet tube, such as the Mapleson configuration, may also be affected. Note that this problem has been exacerbated over the past several years because of the increased use of plastic components, which generally permit deeper engagement than metal fittings, and "low dead space" tracheal tube connectors. Given the opacity of the components and the compressibility and size variations inherent to plastics, it is nearly impossible to visually assure that a given "low dead space" adapter/connector combination is safe.

Obstruction of the exhalation pathway by the fresh gas inlet tube would <u>not</u> occur if one used either (a) a tracheal tube connector which is not of the "low dead space" type (see Figure 4), or (b) a mating adapter which does <u>not</u> have a fresh gas inlet tube protruding into <u>or</u> <u>near</u> the connector area (e.g., the Hustead elbow).

To avoid accidents in operating suites and pediatric critical care units, we suggest the following preventive measures:

- Alert appropriate staff members that if a "low dead space" connection is required, only one of the "low dead space" components (either the adapter or the tracheal tube connector) should be used.

- To further avoid the possibility that these incompatible components will be used together, consider removing from services either the "low dead space" connectors or the "low dead space" adapters with fresh gas inlet tubes.

If you have experience problems associated with "low dead space" devices, we would be most interested to hear about them. Please direct this information to:

Dr. Joseph G. Valentino
Product Problems Reporting Program
The United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852
Toll Free Number: 800-638-6725

Other related technical inquiries may be directed to Mr. E. Donald Walker, C.R.N.A., of my staff at 301-427-7034.

I hope this information will help to prevent further mishaps.

Sincerely yours,

John C. Villforth
Director
National Center for Devices and
Radiological Health