FDA SAFETY ALERT:

GAS/AIR EMBOLISM ASSOCIATED WITH INTRAUTERINE LASER SURGERY

May 11, 1990

To Physicians, Operating Room Personnel, Hospital Administrators and Risk Managers:

This is to alert you to the risk of gas or air embolism when gas, primarily air or CO, is used for cooling the laser fiber tip or for insufflations during therapeutic intrauterine procedures. The emboli are presumably caused when the gas, under pressure, is forced into the vascular system. (Although it may be less likely, this life-threatening situation could also occur in any enclosed body area with vascular access during procedures using gas or air under pressure.)[1, 2]

The FDA learned of this hazard through its Medical Device Reporting system and from the medical literature.[3-5] In one report[5], five cases of gas or air emboli during intrauterine laser surgery were described, four of them fatal. In most cases, the tip of the Nd-YAG laser fiber was cooled with gas or air; in one case, CO_2 was used to insufflate the uterus.

To avoid the possibility of a gas/air embolism during intrauterine laser surgery, it is strongly recommended that gas or air not be used for insufflation or for cooling the laser fiber tip during the procedure. A liquid distention medium provides adequate visualization and will also serve as a cooling agent for the laser fiber tip.

To assure that this message is conveyed to all medical, nursing and technical personnel, FDA suggests posting this Safety Alert or the following WARNING where it will be visible to users of the laser:

WARNING
DURING INTRAUTERINE LASER SURGERY, DO NOT USE GAS OR AIR FOR COOLING THE LASER FIBER TIP OR FOR INSUFFLATION. THIS MAY CAUSE LIFE-THREATENING GAS OR AIR EMBOLISM.

I would appreciate your sharing this Safety Alert with others who might find it useful. Thank you for your help in disseminating this important information.

FDA is interested in learning about any experience associated with gas embolism during intrauterine surgery or other procedures where gas or air is used. Please direct this information to our voluntary Problem Rporting Program, c/o the United States Pharmacopeia, 12601 Twinbrook Parkway, Rockville, Maryland 20852 or call our toll-free number: 1-800-638-6725.

If you have any questions on this Safety Alert, please contact:

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Sincerely yours,

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1. Lasers Surg Med 9:183-185(1989).
2. Intensive Care Med 8:239 (1982).
3. Am J Obstet Gynecol 61(4):877-879 (1989)
4. ECRI Health Devices 18(9):325-326 (1989).
5. Lasers Surg Med 9:581-584 (1989).