U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

"Getting More Information"

Because the following document was developed a number of years ago, the contact information is no longer accurate. If you wish to contact the agency with questions, please use the following:

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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FDA SAFETY ALERT:
Cauda Equina Syndrome Associated with Use of Small-Bore Catheters In Continuous Spinal Anesthesia

May 29, 1992

To Anesthesia Care Providers, Hospital Administrators, Hospital Pharmacists, and Risk Managers:

This is to alert you to a serious hazard associated with continuous spinal anesthesia. Since December 1989, following the initial marketing of small-bore catheters (27 gauge or smaller), FDA has received 11 reports of cauda equine syndrome in which small-bore catheters were used to deliver 5% lidocaine with 7.5% glucose to the intrathecal space. Recent cases have also been reported in the medical literature.[1] This compares with only one reported case of cauda equina syndrome associated with the use of large-bore catheters since 1984. (Cauda equina syndrome is a prolonged and possibly permanent neurological deficit characterized by one or more of the following: loss of bladder and /or bowel control; loss of perineal sensation; decreased sensation or mobility of the lower extremities.)

We are concerned that the use of small-bore catheters in continuous spinal anesthesia is increasing, and thus that the potential for new cases of cauda equina syndrome associated with this technique may be increasing. **Because of these safety concerns, we are advising against the use of any small-bore catheter for continuous spinal administration of any local anesthetic agent**. Please note that this Safety Alert is not directed toward catheters used for other types of drug delivery such as epidural anesthesia, or the use of 5% lidocaine with 7.5% glucose as a single-dose spinal anesthetic injection.

We are also taking action to remove from the market all small-bore catheters distributed for continuous spinal anesthesia. This action affects devices from five manufactures: Kendall Healthcare Products Company, Preferred Medical Products, Concord Laboratories, Inc., Teleflex Medical, Inc., and Medevice, Inc.

If drug or device manufacturers, medical facilities, or physician groups wish to conduct controlled clinical studies demonstrating the safety and efficacy of a specific local anesthetic for continuous spinal anesthesia using small-bore catheters, FDA will consider Investigational New Drug (IND) and Investigational Device Exemption (IDE) applications.

Please share this Safety Alert with colleagues who are involved in anesthesia delivery or follow-up care. If you have medical questions pertaining to this subject please contact: Suzanne Parisian, M.D., Center for Devices and Radiological Health, FDA, 1390 Piccard Drive, HFZ-70, Rockville, Maryland 20850, FAX 301-427-1968.

FDA is interested in further defining this problem. If you are aware of incidents of cauda equina syndrome involving continuous spinal anesthesia, please report them to the Product Problem Reporting Program at 1-800-638-6725.

Sincerely yours,

James S. Benson
Director
Center for Devices and
Radiological Health

1. Rigler ML, Drasner K, Krejcie TC, Yelich SJ, Scholnick FT, DeFontes J, Bohner D. Cauda Equina Syndrome after Continuous Spinal Anesthesia. Anesthesia and Analgesia 1991;72:275-81