

From the Centers for Disease Control

POSTSURGICAL INFECTIONS ASSOCIATED WITH NONSTERILE IMPLANTABLE DEVICES

Two recent cases of postsurgical infection reported to Centers for Disease Control (CDC) occurred after the implantation of devices labeled and sold as nonsterile. Although there was no evidence that the infections resulted from the implant, these occurrences serve as reminders of the importance of monitoring the sterility of implants.

Because manufacturers may supply implantable devices such as orthopedic (e.g., hip prostheses), cardiovascular (e.g., cardiac valve grafts), and neurologic (e.g., shunts) devices as nonsterile, hospital personnel must ensure that these devices are adequately sterilized before implantation. The sterilization process used for an implantable device should be closely monitored and documented in the patient's medical record, including the sterilization method; the duration of exposure to the sterilization agent; conditions such as pressure, temperature, chemical concentration, date, time, and biological monitors; and other process indicators.

Steam or ethylene oxide is recommended for sterilization of implantable devices. Specific manufacturer recommendations for sterilization of the device should be available in the product packaging; if they are not, hospital personnel should contact the manufacturer for sterilization recommendations or to ensure that the sterilization method to be used will not adversely affect device safety and performance. If the information is not available in the product packaging, and recommendations cannot be obtained from the manufacturer, the device should not be used.

Adverse effects associated with implantation of nonsterile implantable devices (received from the manufacturer) must be reported to the manufacturer, who must report the event to the Food and Drug Administration (FDA) by mail (Center for Devices and Radiological Health, FDA User Report, PO Box 3002, Rockville, MD 20847-3002) or by fax ([301] 881-6670). When the manufacturer is unknown, user facilities must report deaths related to implanted devices or adverse effects directly to the FDA at the above address or by fax ([301] 427-1967). To ascertain the extent of complications resulting from infections associated with implantable devices labeled as nonsterile, hospital personnel are requested to report these events through state health departments to CDC's Hospital Infections Program, National Center for Infectious Diseases; telephone (404) 639-1550.

REFERENCE

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From *MMWR*. 1992;41:263.

UPDATE: FOODBORNE LISTERIOSIS, UNITED STATES, 1988-1990

Although outbreaks of invasive disease caused by *Listeria monocytogenes* have been associated with ingestion of a variety of contaminated foods,¹⁻⁵ most listeriosis in the United States occurs as isolated or sporadic cases. To determine the incidence of listeriosis and identify risk factors for disease, during 1988-1990, the CDC collaborated with investigators in four states to conduct active laboratory-based surveillance and special studies in a population of more than 18 million US residents. This report summarizes the findings of these studies.^{6,7}

The study areas included Los Angeles County, the San Francisco Bay area, the Atlanta metropolitan area, four counties in Tennessee, and the state of Oklahoma. Investigators made regular calls to all hospital laboratories and completed case report forms for all residents in whom *L monocytogenes* was isolated from a usually sterile site (e.g., blood, cerebrospinal fluid [CSF], or amniotic fluid).

From November 1988 through December 1990, 301 cases were identified in the surveillance areas, an annual incidence of 7.4 cases per 1 million population; 67 (23%) persons died. Of the 301 cases, 99 (33%) occurred among pregnant women or their newborns. Among the 98 persons with nonperinatal listeriosis for whom information was available, nearly all had at least one immunosuppressive condition, including corticosteroid use (31%), malignancy (29%), renal disease (24%), diabetes (24%), or acquired immunodeficiency syndrome (20%).

Dietary histories of persons with listeriosis identified through the active surveillance project were compared with those of controls matched for age and medical condition (including pregnancy). Patients with listeriosis were more likely than controls to have eaten soft cheeses (odds ratio [OR] = 2.6; 95% confidence interval [CI₉₅] = 1.4-4.8) or food purchased from store delicatessen counters (OR = 1.6; CI₉₅ = 1.0-2.5). Thirty-two percent of sporadic disease could be attributed to consumption of these foods. Eating undercooked chicken also was associated with increased risk in immunosuppressed persons (OR = 3.3; CI₉₅ = 1.2-9.2).⁶

Food obtained from the refrigerators of patients with listeriosis was cultured for *L monocytogenes* using at least two selective enrichment methods, and isolates of *L monocytogenes* from food were compared

with isolates from patients using multilocus enzyme electrophoresis. Overall, 79 (64%) of 123 refrigerators contained at least one food with *L monocytogenes*, and 26 (33%) of the 79 refrigerators with *L monocytogenes* grew the same strain as that which caused illness in a person living in the household. Foods that were ready to eat and foods containing higher concentrations of *L monocytogenes* (those positive by a direct-plating method) were independently associated with an increased likelihood of containing the patient-matching strain.⁷

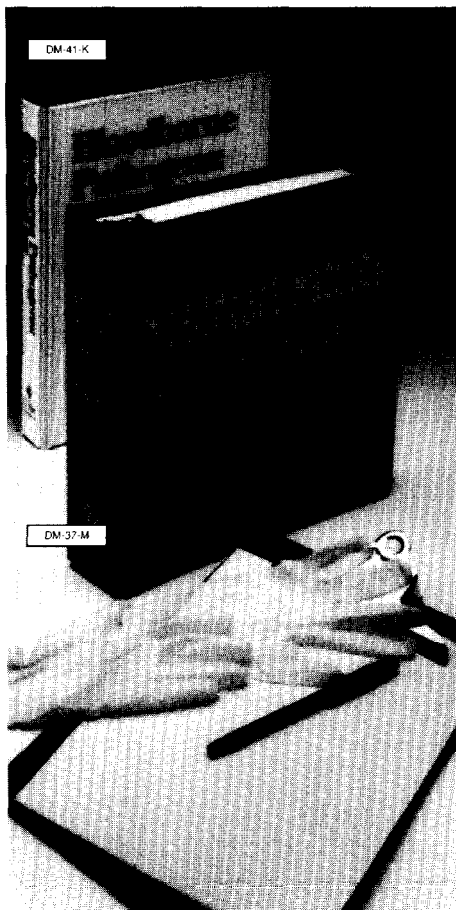
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From *MMWR* 1992;41:251-258.



Assessment: OSHA's new bloodborne pathogens requirements effective 5/5, 6/4, 7/6 of 1992.

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Implementation:

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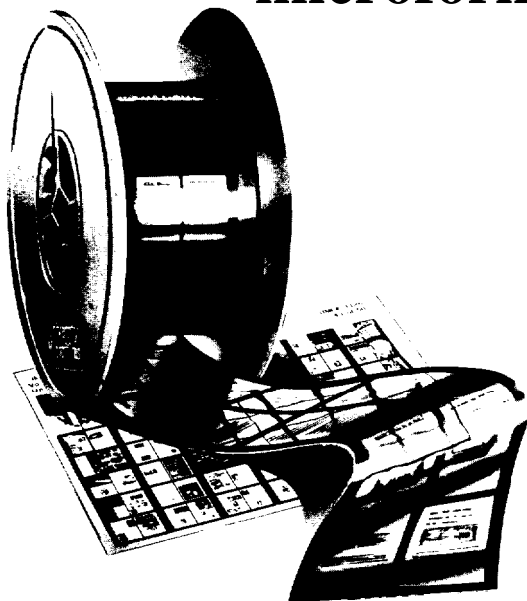
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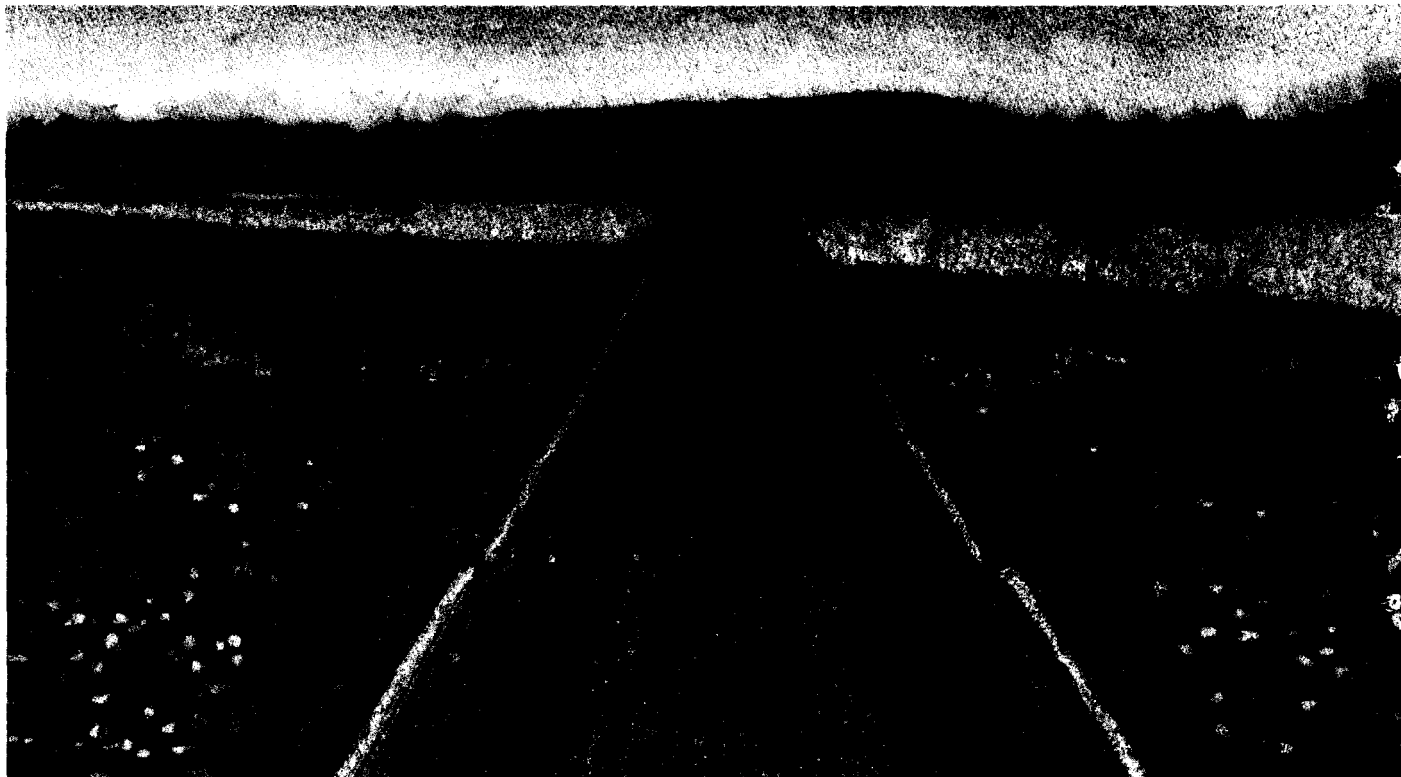
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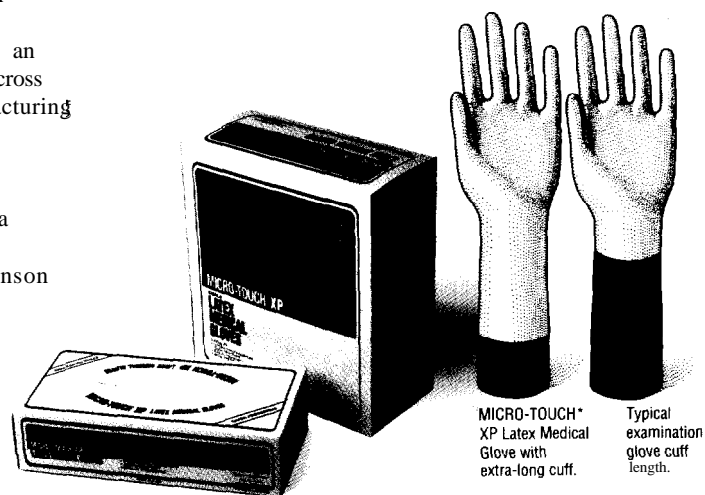
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