



DRS/MtH/IEA.48

28 December 1994

DRS Information Exchange Service**ALERT No. 48****PACEMAKERS - WARNING CONCERNING DANGEROUS WIRING DEFECT**

The Japanese Ministry of Health and Welfare has issued a warning concerning a pacemaker in which the wire of the lead was found to penetrate the outer insulation, leading to cardiac tamponade in implanted patients, some of which were fatal.

The pacemaker is imported into Japan by Century Medical Inc., who first alerted the Ministry to the problem. It is manufactured in the United States of America by Teletronics Pacing Systems Inc.

The Ministry contacted Teletronics and was informed that approximately 42,000 pacemakers have been distributed worldwide since 1987 and 4 cases of cardiac tamponade have been reported, 2 of which were fatal. The manufacturer is investigating the cause of the defective wiring.

In Japan, in 4 pacemakers were found with lead wires which penetrated the outer insulation, and one of them caused cardiac tamponade and shock in the implanted patient.

All products used in Japan are imported from the USA. These are:

Name: Acufix® (screw in) Type J pacing lead for atrium
Model: 330-801
Lot: All
Number: 635. 596 were already implanted, 39 were recalled.
Manufacturer: Teletronics Pacing Systems Inc., USA Miami Plant

Details of products distributed worldwide are as follows:

Model: 330-801, 329-701, 033-812
Lot: All
Number: about 42,000
Manufacturer: A) Teletronics Pacing Systems Inc. USA Miami Plant
B) Teletronics Pty. Limited Australia, Lanecove Plant
C) Teletronica S.A. France, Châtelleraut Plant.

Reference: MHW Urgent Safety News, Inspection and Guidance Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, Tokyo, 16 December 1994.

★ ★ ★