NOTICE TO HOSPITALS
Health Canada Issued Important Safety Information on Active Implantable Medical Devices and Systems

December 19, 2005

To: Hospital Chief of Medical Staff

Please distribute to the relevant Departments of Physiotherapy, Occupational Therapy, Radiology, Rehabilitative Medicine, Surgery, Neurosurgery, Orthopedic Surgery, Biomedical Engineering, Emergency Medicine, Pediatrics, Geriatrics, Internal Medicine, Nursing, Dentistry, Intensive Care and other involved professional staff and **post this NOTICE** in your institution.

Subject: Interactions between active implantable medical devices and systems and other medical devices

This advisory updates previous Notices to Hospitals (October 5, 2005 and October 31, 2005) on this topic, based on recent information provided to Health Canada by device manufacturers and health care providers. The change is highlighted in the table.

Patients with active implantable medical devices and systems (AIMDS) are at risk of injury from interactions between the AIMDS and other medical devices used for diagnostic or therapeutic purposes. Such interactions could damage some AIMDS resulting in loss of therapy from these units, and could cause tissue damage resulting in severe injury or death.

On April 2, 2003, Heath Canada issued a Notice to Hospitals entitled “Important safety information regarding DIATHERMY THERAPY in patients with implanted leads and implanted systems with leads”.[1] It warned about the risks of tissue overheating, serious injury and death in this group of patients when subject to shortwave (radiofrequency) or microwave diathermy therapy. Since then, Health Canada has become aware of further international reports of serious injury resulting from interactions between AIMDS and other medical devices.[2]

In 2003, the French Health Products Safety Agency, Agence française de sécurité sanitaire des produits de santé (AFSSAPS), assembled a working group to analyse the recommendations of AIMDS manufacturers and make recommendations to health care professionals who perform certain diagnostic and therapeutic procedures on patients with AIMDS. The recommendations of the group were released by AFSSAPS in February 2005.[3]

Based on our review of the AFSSAPS report and consultations with manufacturers and healthcare providers, Health Canada has defined AIMDS risk management levels and recommends practices as follows:

Procedure	Type of AIMDS		
	Implanted Cardiac Pacemaker	Implanted Cardiac Defibrillator	Implanted Neurostimulator
Shortwave and Microwave Diathermy	**Absolute contraindication**	**Absolute contraindication**	**Absolute contraindication**
Therapeutic Ultrasound Diathermy	Relative contraindication	Relative contraindication	**Absolute contraindication**
Electromagnetic Stimulation	Relative contraindication	Relative contraindication	**Absolute contraindication**
MRI with transmit/receive radio-frequency (RF) head coil [4]	**Absolute contraindication**	**Absolute contraindication**	*Relative contraindication**
MRI (all other)	**Absolute contraindication**	**Absolute contraindication**	**Absolute contraindication**
Electrosurgery	Relative contraindication	Relative contraindication	Relative contraindication
External Defibrillation	Relative contraindication	Relative contraindication	Relative contraindication
Radiotherapy	Relative contraindication	Relative contraindication	Relative contraindication
Lithotripsy or Ultrasound Therapy	Relative contraindication	Relative contraindication	Relative contraindication
Fluoroscopy or other X-ray procedures	No contraindication	No contraindication	No contraindication
Echography	No contraindication	No contraindication	No contraindication

*This type only of MRI is allowed if both of the following conditions are met:
1)The gradient magnetic field must be 20 T/s or less;
2)The transmit/receive radio-frequency (RF) head coil must have a specific absorption rate (SAR) rating less than the maximum permissible SAR as given in the manufacturer's specifications for the neurostimulator, for all possible radio-frequency (RF) pulse sequences.[4]

Definitions of Levels of Risk Management - AIMDS

No contraindication: The risk of the procedure remains unchanged due to the presence of an AIMDS.

Relative Contraindication: In some circumstances the benefits of the procedures may outweigh its risks. A risk-benefit analysis of the proposed medical procedure, including careful consideration of the alternatives, should be undertaken. Consultation with the referring physician and implanting/monitoring physician should be considered and the labelling of relevant devices (including warnings/precautions) should be reviewed. The exact risks to patients and precautions to be taken in each circumstance are outlined in detail in the AFSSAPS document[3]. In general, if a decision is taken to go ahead with a medical procedure that requires precautions, Health Canada recommends the following:

- if possible, deactivate the AIMDS
- use the lowest device strength compatible with an acceptable diagnostic or therapeutic outcome and keep the path of device output as far from the AIMDS as possible

- monitor the patient closely during the medical procedure
- stop the procedure immediately in the case of an adverse incident
- verify the continued proper function of the AIMDS during and after the medical procedure.

Absolute Contraindication: The procedure should not be used because the risk always outweighs the benefit.

The risk of interactions between AIMDS and other medical devices used for diagnostic or therapeutic purposes depends on many parameters. Due to the diversity and complexity of the devices in question, **Health Canada wishes to pass along these general guidelines but cannot give all-encompassing recommendations that cover all possible clinical scenarios.** The recommendations outlined in this document are based on the information that has been received so far, and Health Canada will keep monitoring this evolving safety issue. The recommendations will be updated as more information will become available.

Health Canada depends on health care professionals to report adverse incidents related to medical devices. Any serious and/or unexpected adverse incident related to medical devices should be reported to Health Canada at the following address:

Health Products and Food Branch Inspectorate
HEALTH CANADA
Address Locator: 2003D
Ottawa, Ontario K1A 0K9
Tel: The Inspectorate Hotline 1-800-267-9675

The Reporting Form and Guidelines can be obtained from the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/rep_md_prob-rap_inc_im_tc-tm_e.html
http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/mavprfmd-rioevraim_tc-tm_e.html

For other inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate (MHPD)
MHPD_DPSC@hc-sc.gc.ca
Tel/Tél: (613) 954-6522
Fax/Télé: (613) 952-7738

References:

1. Important safety information regarding DIATHERMY THERAPY in patients with implanted leads and implanted systems with leads. Notice To Hospitals. Health Products and Food Branch, Health Canada. April 2, 2003. http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2003/diathermy_nth-ah_f.html
2. FDA Public Health Notification: MRI-Caused Injuries in Patients with Implanted Neurological Stimulators. Center for Devices and Radiological Health, Food and Drug Administration. May 10, 2005. http://www.fda.gov/cdrh/safety/neurostim.html
3. Interactions entre dispositifs médicaux implantables actifs et dispositifs médicaux. Agence française de sécurité sanitaire des produits de santé (AFSSAPS). February 2005. http://www.agmed.sante.gouv.fr/htm/5/intdmia/rapport.pdf
4. MRI and Activa Therapy-To the physician, Medtronic Inc. (2005) http://www.medtronic.com/physician/activa/mri.html