MATERIALS LICENSE

Amendment No. 05

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s); and to import such byproduct and source material. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Norwalk Hospital	In accordance with letter dated November 30, 1984
2. Norwalk, Connecticut 06856	3. License number SNM-1504 is amended in its entirety to read as follows:
	4. Expiration date June 30, 1990
	5. Docket or Reference No. 070-01717

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Plutonium (Principal radionuclide Pu-238)	A. Sealed Source(s)	A. 6.25 grams (25 individual sources not to exceed 250 milligrams each)
B. Plutonium (Principal radionuclide Pu-238)	B. Sealed Source(s)	B. 6.25 grams (25 individual sources not to exceed 250 milligrams each)
C. Plutonium (Principal radionuclide Pu-238)	C. Sealed Source(s)	C. 2.1 grams (10 individual sources not to exceed 210 milligrams each)

9. Authorized use

A. Implantation in humans as a component of Coratomic Model C-101 nuclear-powered cardiac pacemakers for clinical evaluation purposes.

B. Implantation in humans in accordance with "Human Implantation Protocal for the Coratomic C-101-P Radioisotope Powered Cardiac Pacer," dated March 2, 1983.

C. Implantation in humans as a component of Medtronic Model 900 nuclear-powered cardiac pacemakers for clinical evaluation purposes.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities, at Norwalk, Connecticut 06856.

11. The specified possession limit includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients or otherwise in use.

12. The licensee shall not receive or transfer in any single transaction one (1) gram or more of plutonium 238 contained in nuclear-powered pacemakers without notifying the Division of Safeguards, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, and, in addition, completing and distributing Form NRC-741 as required by Section 70.54 of 10 CFR 70.

ML10

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: SNM-1504
Docket or Reference number: 070-01717
Amendment No. 05

(continued) CONDITIONS

13. The licensee shall report to the U. S. Nuclear Regulatory Commission, Region I, Nuclear Materials Section, 631 Park Avenue, King of Prussia, Pennsylvania 19406, within twenty-four (24) hours of occurrence, the death of any nuclear pacemaker patient, and any adverse reaction and/or malfunction involving a pacemaker system, including the leads. A written report giving details of the adverse reaction and/or malfunction shall be submitted within thirty (30) days.

14. The licensee shall report to the U. S. Nuclear Regulatory Commission, Region I, Nuclear Materials Section, 631 Park Avenue, King of Prussia, Pennsylvania 19406, within ten (10) days, loss of contact with a nuclear pacemaker patient.

15. The licensee shall continue patient follow-up and replacement procedures for the nuclear pacemaker during the life of the patient. Procedures for recovery and authorized disposal of the nuclear pacemaker by return to the manufacturer shall be followed upon the death of the patient.

16. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in letters dated November 30, 1984 and May 29, 1985. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U.S. Nuclear Regulatory Commission

Date JUN 24 1985

By Original Signed By:
John D. Kinneman

Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406