Norwalk Hospital

Norman A. Brady
President

Norwalk,
Connecticut 06856

November 30, 1984

United States Nuclear Regulatory Commission
Region 1
641 Park Avenue
King of Prussia, Pennsylvania 19406

Attention: John E. Glenn, Ph.D.
Materials Licensing Branch

RE: License No. SNM - 1504 Renewal

Gentlemen:

Request is made to renew license No. SNM-1504 authorizing the use of plutonium-238 nuclear pacemakers at this facility.

The reasons for renewal are to:

1. Continue to receive and implant nuclear pacemakers.
2. Follow patients with implanted nuclear pacemakers and,
3. Return explanted nuclear pacemakers to their manufacturer for proper disposal.

Please be advised that the manufacturer's pacemakers are as follows:

Manufacturer	Model No.	Milligrams of Plutonium 238
Coratomic	C-101 and C-101-P	250 each
Medtronics	9,000	210 each

Authorization for ten (10) Nuclear pacemakers of each manufacturer is requested. The manufacturer's NRC approved protocol will be followed.

Martin Krauthamer, M.D., Chief, Section of Cardiology, is the physician in charge of the plutonium pacemaker program. The nuclear pacemakers will be used only by or under the direct supervision of Dr. Krauthamer.

If there should be any questions, please contact me.

Very truly yours,

N. A. Brady

Norman A. Brady

Enclosure
cc: C. Collica, M. Krauthamer, M.D., C. Palestro, M.D.

PROCEDURE FOR IMPLANTING NUCLEAR-POWERED PACEMAKERS

Both the hospital and the physicians must be licensed to implant Coratomic nuclear-powered pacemakers. A suggested format for a license application is included as Exhibit IX in the Human Implantation Protocol for the Coratomic C-101-P Radioisotope Powered Cardiac Pacer, dated March 2, 1983.

As part of the license application, the physicians and the hospital must agree to follow the Human Implantation Protocol for the Coratomic C-101-P Radioisotope Powered Cardiac Pacer, dated March 2, 1983. One provision of the protocol is that the physician or hospital and the patient must remain in contact with one another until the patient dies or until the Coratomic radioisotope-powered cardiac pacer is removed. In the event of patient death or pacemaker removal, the pacemaker must be recovered by the physician or hospital and returned to Coratomic.

The requirements for patient follow-up contact and pacemaker recovery are stated in sections 2, 3, 7 8, 9, 10, 11, 12, 13, and 14 of the C-101-P protocol. Please note that Coratomic and the licensing agency (The licensing agency is usually the U. S. Nuclear Regulatory Commission. In the case of agreement states, it is the state licensing agency.) must be notified of a patient death within 24 hours, and must be advised of loss of contact with a patient within 10 days.

PROCEDURE FOR IMPLANTING NUCLEAR-POWERED PACEMAKERS

(continued)

The license application should be typed on the hospital's letterhead, and signed by the hospital administrator, the hospital radiation safety officer, and each of the physicians involved. Then the license application is mailed to the licensing agency.

After the hospital receives their license, a copy should be mailed to the Coratomic Data Center. Coratomic must have a copy of the license on file before an isotopic-powered pacemaker can be shipped to the hospital.

AGREEMENT STATES

1. Alabama
2. Arkansas
3. Arizona
4. California
5. Colorado
6. Florida
7. Georgia
8. Kansas
9. Kentucky
10. Louisiana
11. Maryland
12. Mississippi
13. Nebraska
14. Nevada
15. New Hampshire
16. New York
17. North Carolina
18. North Dakota
19. Oregon
20. South Carolina
21. Tennessee
22. Texas
23. Washington

If an Agreement State, application and Letter of Choice sent to the appropriate office in that state, instead of to the N.R.C. for approval.

All government hospital licenses are sent to the N.R.C. in Washington, DC for approval, even if it is an Agreement State.

HUMAN IMPLANTATION PROTOCOL

FOR

THE CORATOMIC C-101-P

RADIOISOTOPE POWERED CARDIAC PACER

March 2, 1983

Coratomic
P. O. BOX 434, INDIANA, PENNSYLVANIA 15701
PHONE (412) 349-1811 • TELEX 86-6658

TABLE OF CONTENTS

SUBJECT

CORATOMIC C-101-P

RADIOISOTOPE CARDIAC PACER PROTOCOL

March 2, 1983

1. Description of the Pacer and Radionuclide Power Source

An extensive literature has arisen in connection with cardiac pacing, and selected references are listed in Exhibit 1. The physician responsible for pacer implantation is cognizant of these and other relevant references and has had extensive experience in the use of cardiac pacers.

The C-101-P pacer utilizes a programmable hybrid circuit, the pacing modes and operating parameters of which can be noninvasively changed using a Coratomic hand-held programmer. It is electronically similar to programmable pacers which have been in use for many years. While the unit is normally used as an R-wave inhibited (VVI) pacemaker, the implanting physician may elect to use the pacer for asynchronous (VOO) pacing when appropriate indications are present.

The pacing rate is programmable at 13 settings ranging from 38 to 120 PPM. Pulse current can be set to either 4 or 10 mA. Sensitivity is programmable to 1.5, 2.5, 4, or 5 mV. The pacer can be changed from its normal R-wave inhibited (VVI) mode to asynchronous (VCO) pacing by placing the sensitivity selector to its FR (Fixed Rate) setting.

The unit is hermetically sealed and shielded against electromagnetic interference. It has an asynchronous "magnet rate", identical to the programmed pacing rate, used to ascertain cardiac capture and for operational verification. If high energy electromagnetic fields are present, the pacer will switch to a fixed rate rather than becoming inhibited.

The fuel used for the C-101-P is plutonium-238 in its oxide form, pressed and sintered into a hard, ceramic pellet. The isotopic battery has been so designed that excess electrical power is available at the end of a 40 year life. The pacers have undergone extensive testing for efficacy, including excessive mechanical shock, impact, and vibration testing, and the nuclear fuel is contained in such a manner to prevent fuel release under any credible accident, including building or auto accident, fire, fall from an airplane, crushing, corrosion in sea water, or accidental cremation.

Data concerning radiation level, safety, and efficacy testing is on file with the United States Nuclear Regulatory Commission, as a Master Protocol.

2. Patient Selection

Cooperative and reliable patients, who are stable, and non-mobile members of the community, will be selected to assure accurate long-term follow-up reporting.

3. Follow-Up and Reporting

The physician or hospital will be required to contact the patient at least every six months, and report the contact to Coratomic. This contact will be maintained during the life of the patient or until the pacer is removed. "In-person" follow-up visits are preferable; however, telephone contacts are acceptable. At the time of follow-up, patients should be reminded of the importance of carrying their I. D. card and wearing their I. D. jewelry. Any complications or adverse reactions must be reported to Coratomic by the physician or hospital. Coratomic will consolidate the reporting of patients and notify the Nuclear Regulatory Commission of the results of its accountability program twice per year. If the patient's whereabouts are unknown, Coratomic will, through its contacts with the hospitals and physicians, locate the patient and forward this information to the hospitals to provide complete accountability.

4. Implantation Procedures and Leads

Conventional methods of pacemaker insertion are to be used, ensuring as far as possible that the electrodes and leads used have an expected life comparable to the pacemaker and that they have appropriate pacing thresholds. In patients with an existing lead, the type of existing electrode must be compatible. If not, standard adapters may be used. Spliced leads may not be used. Ideally, Coratomic leads should be utilized to assure long-term compatibility with the pacer materials. Myocardial or endocardial leads may be used with any of the standard surgical approaches for lead implantation in either the left or the right ventricle. The C-101-P pulse generator may be implanted in the subcutaneous tissue of the abdomen, chest wall, the subpectoral muscle tissue of the chest wall, or any other area deemed suitable by the responsible physician.

5. Stimulation Threshold Measurements

The pacing threshold will be tested for all electrodes, old or new, utilizing a battery-operated, calibrated ($\pm$5% accuracy) pulse generator with an adjustable amplitude and of a pulse duration of .8 to 1.2 milliseconds.

Only those electrodes may be utilized in which a threshold is demonstrated no greater than 1.5 mA if newly implanted or 4.0 mA if chronically implanted, whether transvenous or epicardial, measured at a pulse width of

1.0 milliseconds.

6. Sensing Measurements

If possible, the amplitude and width of the patient's QRS wave should be measured. Measurement should be between a ground plate in the pacer subcutaneous pocket and the lead terminal distal to the heart.

7. Registration and Implant Reports

Immediately upon implantation of the C-101-P, the physician or hospital will complete a Registration and Implant Data Form, and forward it within 10 days to the Coratomic Data Center. The form includes identification of the pacemaker, the patient, the physician, the hospital, the heart lead and adapter (if used), stimulated rate, and clinical data concerning the patient and his or her cardiac disease. The data form is shown as Exhibit II, attached.

8. Follow-up Data

The follow-up data, reported at six-month intervals, will be prepared by the physician or hospital and submitted to the Coratomic Data Center on the Follow-up Data Form (see Exhibit III, attached). This form summarizes information on the patient and lists any complications, adverse reactions or pacer malfunction. "In-person" follow-up visits are preferable; however, telephone contacts are acceptable. At the time of follow-up, patients should be reminded of the importance of carrying their I. D. card and wearing their I. D. jewelry.

9. Reports of Removal and Replacement

A special form, "Pacer Failure and Removal or Patient Death," (Exhibit IV) is provided. This form records all pertinent required data concerning the patient, physician, hospital and reasons for pacer removal and replacement, including whether the failure was of battery, electronic, or lead origin. Corrective procedures and results of patient examinations are also required.

In the event of pacer removal, the pacer must be recovered and returned to Coratomic. The hospital and/or the physician shall notify Coratomic, and the licensing agency, of the pacer removal, and Coratomic will send the proper shipping container and instructions to the explanting institution for the pacemaker's return.

10. Notification of Deaths, Adverse Reactions or Malfunctions

Notification of death is included in the form "Pacer Failure and Removal or Patient Death" (Exhibit IV). The cause of death and autopsy findings are included.

In the event of patient death, the pacer must be recovered and returned to Coratomic. The hospital and/or the physician shall notify Coratomic, and the licensing agency, of the patient death and pacer removal within 24 hours of such occurrence, and Coratomic will send the proper shipping container and instructions to the explanting institution for the pacemaker's return. Coratomic will immediately notify the Nuclear Regulatory Commission of the patient death.

11. Notification of Loss of Patient Contact

The hospital must notify Coratomic, and the licensing agency, within ten days of the loss of contact with a nuclear powered pacemaker patient. This notification can be made on the Follow-up Data Form, Exhibit III, which outlines the reasons for loss of contact and steps taken to reestablish contact. When loss of contact is reported, Coratomic will immediately notify the Nuclear Regulatory Commission and will pursue the patient using data from the initial implant form (Exhibit II) until a satisfactory explanation is obtained. Coratomic will advise the hospital of their findings.

12. Information To and Consent From the Patient

a. All patients accepting the pacemaker must agree to maintain contact with the physician or hospital as summarized above and to the removal and return to the physician (and from them to Coratomic) of the unit upon completion of its expected useful life (40 years), its failure, or upon the patient's death, whichever occurs first. A legally binding document (Exhibit V) will be signed by the patient, a witness, the patient's spouse, and/or a relative of the patient.

b. The patient will be required to carry an identification card as stated in the form shown in Exhibit V. This card is shown in Exhibit VI. The card will identify the carrier as a radioisotope powered cardiac pacer patient, will specify the manufacturer and model number of the patient's pacemaker, specify the radionuclides contained in the pacer, and present explicit instructions for notification of responsible parties in the event of accident or difficulty. At the time of follow-up, patients should be reminded of the importance of carrying their I. D. card. The patient will also be required to carry a uniform anatomical Gift Act Card, as shown in Exhibit VII. If the patient has not attained majority age, the agreement card shown in Exhibit VIII should be executed by the patient where possible and his or her legal guardian.

c. The patient will also be required to carry an identification bracelet or other equivalent jewelry of the medical-alert type which will carry the same patient's name and a statement to call the proper emergency

telephone number. At the time of follow-up, patients should be reminded of the importance of wearing their I. D. jewelry. This medical alert jewelry is mentioned in Exhibits III and IV.

d. The patient will maintain contact with the physician or hospital as discussed in 2 above, and he will be required to agree to do so on the informed consent form of Exhibit V.

e. The patient will notify the hospital of any change either in his/her address or in the names and addresses of two persons to be contacted if the patient cannot be located. The patient will be required to agree to do so on the informed consent form (Exhibit V).

f. The patient will be required to notify the hospital of his intention to travel in foreign countries. The hospital will in turn notify Coratomic, who will notify the Nuclear Regulatory Commission. The patient agrees to provide this information on the Informed Consent Form (Exhibit V).

13. Record Retention

All pacer records will be maintained separately from the routine hospital records, either by a centralized authority so designated, health physics personnel, or the pacemaker clinic within the hospital's jurisdiction, or the physician responsible for the implantation program.

The hospital or the implanting physician will notify Coratomic of any change in the patient's address or condition so that Coratomic may maintain current records on the patient.

The patient's chart, both at the hospital and in the physician's office, must prominently indicate that the pacemaker must be returned to Coratomic upon its removal from the patient for any reason.

14. Accountability and Recovery

Under a special nuclear material license issued for implanting radioisotopic pacemakers, the patient's hospital assumes the responsibility for the control, accountability and recovery of the special nuclear materials (plutonium) in the pacemaker. Conditions for accountability and recovery include the following:

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

b. The hospital shall report to Coratomic, Inc. (the manufacturer of the pacemaker), and to the licensing agency, within 24 hours of occurrence, the death of any nuclear-powered pacemaker patient. Coratomic will immediately advise the Nuclear Regulatory Commission.

c. The hospital shall report to Coratomic, Inc., and to the licensing agency, within 10 days, the loss of contact with a nuclear-powered pacemaker patient. Coratomic will immediately advise the Nuclear Regulatory Commission.

d. The implanting hospital should normally be able to follow a patient for life, considering that non-mobile patients are selected and that telephone contacts may be used for follow-up. In unusual cases where follow-up difficulties are experienced, Coratomic should be contacted to try to arrange transfer of responsibility to another hospital. Responsibility could be transferred to another hospital if:

(1) The new hospital is properly licensed and agrees in writing to accept full responsibility in accordance with the protocol;

(2) The old hospital transfers responsibility in writing;

(3) The patient signs revised consent forms and receives revised I. D. card and I. D. jewelry;

(4) The appropriate licensing agencies are notified of the transfer and provided copies of the documentation.

Following a proper transfer, the old hospital may of course amend or terminate its license as appropriate.

REFERENCES

1. Smyth, Nicholas P. D.: Cardiac Pacemaking. *Surgical Diseases of the Chest*, Second Edition in Press, Editor Brian Blades., C. V. Mosby Co., St. Louis, Mo., 1974.

2. Chardack, William M.: Cardiac Pacemakers and Heart Block. *In Surgery of the Chest* (Chapter 38), Second Edition, Editors John H. Gibson, Jr., David C. Sabiston and Frank C. Spencer. W. B. Saunders Co., Philadelphia, Pa., 1969.

3. Furman, Seymour, and Escher, Doris J. W.: *Principles and Techniques of Cardiac Pacing*. Harper and Row, New York, N.Y., 1970.

4. Thalen, Hilbert J.: *The Artificial Cardiac Pacemaker*: Its History, Development and Clinical Application. C. C. Thomas, Springfield, Ill., 1969.

5. Hurzeler, Philip; Decaprio, Vincent; and Furman, Seymour, Montefiore Hospital and Medical Center, New York, N.Y.: *Endocardial Electrograms and Pacer Sensing;* paper presented at AAMI 10th Annual meeting March 17–18, 1975.

EXHIBIT X
INSTRUCTIONS FOR HOSPITAL OR CLINIC TELEPHONE OPERATORS
CORATOMIC C-100 SERIES ISOTOPIC PULSE GENERATOR

Nuclear Pacemaker

Instructions to Operator:

1. Accept any collect call with reference to a Nuclear Pacemaker.

2. Any call concerning a Nuclear Pacemaker involves a patient with a nuclear pacemaker and requires immediate action to insure that there is no danger of radiation exposure and recovery of the nuclear pacer.

3. Obtain as much information from the caller as is possible including:

   Caller's Name and Where he may be Reached.

   Patient's Name, Status, and Where he may be Reached.

   Attending Physician (if any) and Where he may be Reached.

   Information from Patient I. D. Card

   Patient's Social Security No. _____

   Date of Implant _____

   Pacer Serial Number _____

4. Notify immediately: _____

_____

Name, address, telephone number of physician responsible

If he cannot be reached, notify: _____

_____

Name, address, telephone number of alternative physician.

If neither can be reached, contact physician on duty for the Cardiac Care Unit; inform him that this involves a nuclear pacer; and advise him of the information you have and the urgency of the matter.

EXHIBIT IX
(continued)

9. Describe the applicant's procedures to assure notification of appropriate individuals upon receipt of an emergency report of inquiry concerning a pacemaker bearer. Include written instructions to be given to telephone operators.

10. Confirm that the physicians responsible for and participating in the implantation program represent that they are familiar with the Coratomic C-101-P Protocol and the Coratomic C-101-P Pacer and understand that the issuance of a license is conditional upon the following of this protocol.

11. Confirm that the applicant institution agrees to continue the follow-up reporting and recovery procedures during the life of the patient and until the pacemaker is recovered and returned to Coratomic, Inc., P. O. Box 434, Indiana, PA 15701, even in the event the physicians named in the application are no longer associated with the applicant.

12. Confirm that packaging, labeling, and shipping instructions to be furnished by Coratomic, Inc. will be followed upon the return of the pacemaker for approved disposal.

13. The applicant hospital or medical institution hereby requests a license to receive, possess, store, and implant the Coratomic C-101-P nuclear powered pacemaker in accordance with this application.

Signed: Applicant: _____
(Hospital or Medical Institution)

By: _____
(name and title of individual signing on behalf of the applicant)

Physicians responsible for implantation program:

_____

(Letter should be signed by both an officer of the applicant and the physicians responsible for the implantation program. Type or print names under signatures.)

EXHIBIT IX
SUGGESTED APPLICATION FORMAT FOR NUCLEAR POWERED PACEMAKERS
CORATOMIC C-101-P ISOTOPIC PULSE GENERATOR

Send to:

Material Licensing Branch
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Or - Agreement State Licensing Agency
(if appropriate)

Re: Application for license to participate in the implantation of Coratomic C-101-P nuclear powered pacemakers, each containing 250 milligrams of Pu-238(<4.3 curies).

Gentlemen:

The following information is submitted in application for a license to participate in the implantation of Coratomic C-101-P nuclear powered pacers.

1. Applicant: _____
(Hospital or Medical Institution)

_____
(Address)

_____
(State and Zip Code)

2. Physicians responsible for implantation program: (Provide this information for EACH physician involved)

Name:
Office Address:
Telephone Number:
State Licensed in Which to Practice:
Specialty Board Certification:
Position with the Applicant:
Previous experience in the implantation and follow-up of pacemakers by physician:
(include duration of pacemaker experience, total number of implants physician has done, and the total number he has done at the applicant's facilities.)

3. Protocol to be followed:
HUMAN IMPLANTATION PROTOCOL FOR THE CORATOMIC C-101-P RADIOISOTOPE POWERED CARDIAC PACER, DATED MARCH 2, 1983.

4. A maximum of ___ Coratomic C-101-P pacemakers is requested to be implanted annually.

5. Description of physical facilities and equipment at the applicant institution or hospital:
(Include description of cardiac care unit and operating facilities and list specific equipment needed and available for the implantation program; include equipment for measuring stimulation thresholds, threshold parameters, and overall pacemaker function.)

6. Description of applicant's present pacemaker implantation and follow-up program: (Include size, i. e., number of patients, and duration.)

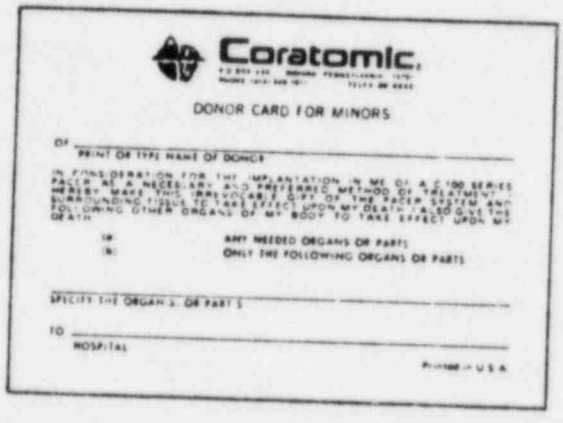
7. Describe methods applicant will establish to maintain records of implantation and follow-up of patients separate from routine hospital records. (Include procedures for assuring continuity of follow-up and determining any possible loss of follow-up with a patient.)

8. Confirm that the applicant institution or hospital will establish appropriate control procedures to insure the physical security of the pacemakers while in the possession of the applicant. These procedures will include keeping track, by serial number, of the location of each pacemaker and requiring that they be kept under lock and key when not being used to guard against loss or theft. Confirm that all activities will be conducted in accordance with the regulations under Title 10, Code of Federal Regulations, Part 70.

(continued next page)

EXHIBIT VIII
DONOR CARD FOR MINORS
CORATOMIC C-100 SERIES ISOTOPIC PULSE GENERATOR

(Front)


Coratomic

DONOR CARD FOR MINORS

OF _____
PRINT OR TYPE NAME OF DONOR

IN CONSIDERATION FOR THE IMPLANTATION IN ME OF A C-100 SERIES PACER AS A NECESSARY AID PREFERRED METHOD OF TREATMENT, I HEREBY MAKE THIS IRREVOCABLE GIFT OF THE PACER SYSTEM AND SURROUNDING TISSUE TO TAKE EFFECT UPON MY DEATH. I ALSO GIVE THE FOLLOWING OTHER ORGANS OF MY BODY TO TAKE EFFECT UPON MY DEATH

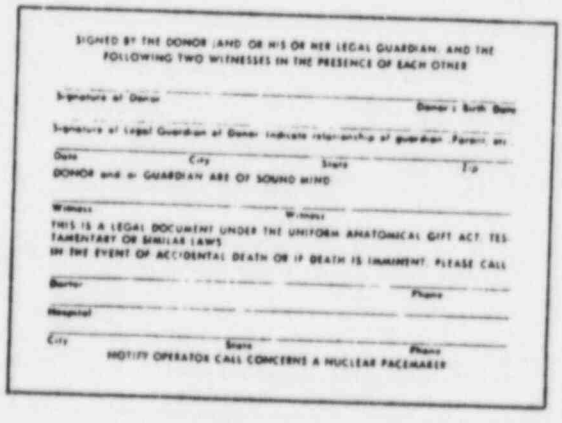
(a) ANY NEEDED ORGANS OR PARTS
(b) ONLY THE FOLLOWING ORGANS OR PARTS

_____
SPECIFY THE ORGAN S OR PART S

TO _____
HOSPITAL

Printed in U S A

(Back)


SIGNED BY THE DONOR (AND OR HIS OR HER LEGAL GUARDIAN) AND THE FOLLOWING TWO WITNESSES IN THE PRESENCE OF EACH OTHER

Signature of Donor _____ Donor's Birth Date

Signature of Legal Guardian of Donor (indicate relationship of guardian) Parent, etc.

Date _____ City _____ State _____ Zip

DONOR and or GUARDIAN ARE OF SOUND MIND

Witness _____ Witness _____

THIS IS A LEGAL DOCUMENT UNDER THE UNIFORM ANATOMICAL GIFT ACT, TESTAMENTARY OR SIMILAR LAWS
IN THE EVENT OF ACCIDENTAL DEATH OR IF DEATH IS IMMINENT, PLEASE CALL

Doctor _____ Phone

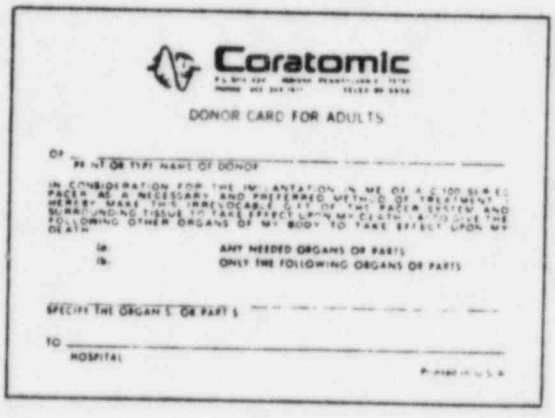
Hospital _____

City _____ State _____ Phone

NOTIFY OPERATOR CALL CONCERNS A NUCLEAR PACEMAKER

EXHIBIT VII
DONOR CARDS FOR ADULTS
CORATOMIC C-100 SERIES PULSE GENERATOR

(Front)


Coratomic

DONOR CARD FOR ADULTS

OF
PRINT OR TYPE NAME OF DONOR

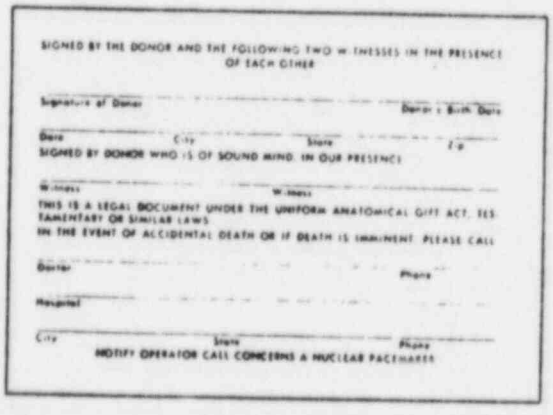
IN CONSIDERATION FOR THE IMPLANTATION IN ME OF A C-100 SERIES PACER AS A NECESSARY AND PREFERRED METHOD OF TREATMENT I HEREBY MAKE THIS IRREVOCABLE GIFT OF THE PACER SYSTEM AND SURROUNDING TISSUE TO TAKE EFFECT UPON MY DEATH AND/OR THE FOLLOWING OTHER ORGANS OF MY BODY TO TAKE EFFECT UPON MY DEATH

(a) ANY NEEDED ORGANS OR PARTS
(b) ONLY THE FOLLOWING ORGANS OR PARTS

SPECIFY THE ORGAN S OR PART S

TO
HOSPITAL

(Back)


SIGNED BY THE DONOR AND THE FOLLOWING TWO WITNESSES IN THE PRESENCE OF EACH OTHER

Signature of Donor
Donor s Birth Date

Date
City
State
Zip

SIGNED BY DONOR WHO IS OF SOUND MIND IN OUR PRESENCE

Witness
Witness

THIS IS A LEGAL DOCUMENT UNDER THE UNIFORM ANATOMICAL GIFT ACT, TESTAMENTARY OR SIMILAR LAWS

IN THE EVENT OF ACCIDENTAL DEATH OR IF DEATH IS IMMINENT PLEASE CALL

Doctor
Phone

Hospital

City
State
Phone

NOTIFY OPERATOR CALL CONCERNS A NUCLEAR PACEMAKER

EXHIBIT VI
PATIENT IDENTIFICATION CARDS
CORATOMIC C-100 SERIES ISOTOPIC PULSE GENERATORS

(Front)

Coratomic.

NAME _____

ADDRESS _____

CITY _____ STATE _____ ZIP _____

PHONE _____ SOC SEC NO _____

PACER MODEL _____ SERIAL NO _____

DATE OF IMPLANT _____ PACER RATE _____

TYPE OF LEAD _____

(Back)

I HAVE AN IMPLANTED CORATOMIC® RADIOISOTOPE POWERED CARDIAC PACER. IT CONTAINS LESS THAN 4.1 CURIES OF PLUTONIUM 238. GOVERNMENT REGULATIONS REQUIRE PACER REMOVAL AND RETURN UPON DEATH.

RADIOACTIVE

IN CASE OF EMERGENCY, HOSPITALIZATION OR DEATH CALL COLLECT INFORM OPERATOR CALL CONCERNS A NUCLEAR PACER

PHYSICIAN _____

HOSPITAL _____

ADDRESS _____

PHONE _____

Printed in U.S.A.

EXHIBIT V

INFORMED CONSENT FOR SURGICAL IMPLANTATION
OF RADIOISOTOPE POWERED CARDIAC PACER
CORATOMIC C-100 SERIES ISOTOPIC PULSE GENERATOR

I understand that for the treatment of my cardiac condition - a disturbance of normal cardiac conduction - a cardiac pacer is to be implanted in me. I understand that the surgical procedure may/will require the implantation of a new electrode or lead into or onto the surface of my heart. While the surgical procedure is not of unreasonable risk, the possibility of complications or even death exist. The procedure has been explained to me, and I have had the opportunity to ask any questions concerning it.

I understand that the pacer to be used for the implantation is a radioisotope powered cardiac pacer manufactured by Coratomic. Although the pacer has been extensively tested, there is no assurance that its components will last the full design life. On the basis of past experience, units of this type are expected to have a reliable life expectancy in excess of 40 years. I understand that the cardiac pacer does produce radiation, but that this radiation is negligible.

Since the device contains radioisotope material (Plutonium-238), ultimately, after my death or earlier, if the useful life of the pacer is exceeded, if it ceases to function effectively for my medical needs, or if I request to have it removed, the pacer must be returned to Coratomic via _____ (licensed institution). Accordingly, I agree to contact _____ (institution) at least every six months, and whenever I change my residence. I will always carry the appropriate identification card on my person, and will at all times carry the Uniform Anatomical Gift Act donor card and wear either a medical alert bracelet or its equivalent.

Notwithstanding my contacting the implanting institution following the insertion of a cardiac pacer of any sort, I am advised to remain in contact with my personal physician.

I agree to notify the hospital, who will, in turn, notify Coratomic of my intention to travel in foreign countries. Coratomic will, in turn, notify the Nuclear Regulatory Commission.

I agree to provide the hospital with the names, addresses, and telephone numbers of two persons to be contacted if I cannot be located. I also agree to notify the hospital of any changes in the names, addresses, or telephone numbers of the two persons to be contacted.

I agree to maintain contact with my physician at least every six months following the insertion of the pacer. Furthermore, I consent to disclosure by the clinic or Coratomic of any information acquired by the clinic in regard to the implantation of the radioisotope powered cardiac pacer, provided, however, in no event shall disclosure other than to Coratomic include my identification without my specific written approval.

I have had the opportunity to ask questions pertaining to the surgical procedure, the radioisotope powered cardiac pacer, and the follow-up procedure. The possible alternate methods of treatment, including the use of conventional chemical battery powered pacers have been called to my attention.

With these facts in mind and intending to be legally bound, I hereby authorize the surgical procedure whereby the Coratomic radioisotope powered pacer will be implanted in me waiving the right to claim that such procedure was not properly authorized, and I agree to the follow-up procedures and to the ultimate return of the unit as detailed above.

_____
Witness (Date)

_____
Patient's signature or person authorized to consent for the patient (Date)

_____
Relationship to the patient signing if other than the patient

Please sign 3 copies:

1 copy to patient
1 copy to hospital
1 copy to Coratomic

I certify that I have explained the above procedure

_____
Dr. (Date)

EXHIBIT IV

PACER FAILURE AND REMOVAL
OR PATIENT DEATH FORM
CORATOMIC C-100 SERIES ISOTOPIC PULSE GENERATOR

IMPORTANT: The isotopic pacemaker must be recovered and returned to Coratomic in the event of patient death or pacemaker removal. Please contact Coratomic for proper shipping container.

Please complete this form. Retain one copy for your records and return one copy to:

CORATOMIC, INC.
DATA CENTER
P. O. Box 434
Indiana, PA 15701

1. Patient Name _____
Last First Initial
Social Security No. _____ Patient Hospital Record No. _____
Pulse Generator Serial No. _____ Date of Implantation _____
Date of Follow-up _____
Name of Physician _____
Name of Hospital _____ Telephone No. _____
Address _____
City _____ State _____ Zip _____
Patient has I. D. card: Yes ___ No ___
Patient is wearing Bracelet or its Equivalent: Yes ___ No ___
How was pacemaker disposed of? _____
2. Pacer Failure
Battery Failure ___ Lead Failure ___ Electronics Failure ___
Description of Failure _____
_____
Corrective Procedure Due to Failure
Replaced Pacer ___
Model and Serial Number of Replacement _____
Replaced Lead ___
Model and Serial Number of Replacement Lead _____
3. Patient Death
Causes of Death _____
_____
_____
Autopsy Findings _____
_____
_____
_____
Was Pacer functioning at time of death? Yes ___ No ___
Was Lead functioning at time of death? Yes ___ No ___
4. Summary of Medical Examinations (if other than death) _____
_____
_____
_____
_____
_____

EXHIBIT III

FOLLOW-UP DATA FORM

CORATOMIC C-100 SERIES ISOTOPIC PULSE GENERATOR

Please complete this form. Retain one copy for your records and return (within 10 days) one copy to:

CORATOMIC, INC.
DATA CENTER
P. O. Box 434
Indiana, PA 15701

IMPORTANT: The Isotopic pacemaker must be recovered and returned to Coratomic in the event of patient death or pacemaker removal. Please contact Coratomic for proper shipping container.

1. Patient Name _____
Last First Initial

Social Security No. _____ Hospital Record No. _____

Home Address _____

_____ A/C & Phone _____

Business Address _____

_____ A/C & Phone _____

Name, address, and telephone of person(s) to be contacted if patient cannot be located _____

_____ A/C & Phone _____

Relationship to Patient _____

Name, address, and telephone of alternate person(s) to be contacted if patient cannot be located _____

_____ A/C & Phone _____

Relationship to Patient _____

2. Physician(s) and Hospital:

Name _____

Office Address _____

_____ A/C & Phone _____

3. Radioisotope Powered Pacer Information:

Serial No. _____ Date of Implant _____

Date of Follow-Up _____

Was follow-up an "in-person" visit or telephone contact? _____

Was patient reminded of the importance of carrying I. D. card and wearing I. D. jewelry? Yes No

Patient has I. D. card Yes ___ No ___

Patient is wearing Bracelet or its Equivalent: Yes ___ No ___

C-100 Series Pacer Information: Satisfactory ___ Unsatisfactory ___

Stimulation Rate: with Magnet _____

without Magnet _____

List any complications, adverse reactions, or pacer malfunction:

_____

_____

_____

Has any repair, relocation or replacement of leads been necessary? yes/no

Has satisfactory contact been maintained with the patient for follow-up and accountability purposes? Yes ___ No ___

If no, why was contact lost? _____

What steps have been taken to re-establish contact? _____

_____

EXHIBIT II

REGISTRATION AND IMPLANTATION DATA FORM
CORATOMIC C-100 SERIES ISOTOPIC PULSE GENERATOR

Please complete this form. Retain one copy for your records and return(within 10 days) one copy to:

CORATOMIC, INC.
DATA CENTER
P. O. Box 434
Indiana, PA 15701

IMPORTANT: The isotopic pacemaker must be recovered and returned to Coratomic in the event of patient death or pacemaker removal. Please contact Coratomic for proper shipping container.

(please print or type)

1. Patient Name _____
Last First Initial
Social Security No. _____ Hospital Record No. _____
Home Address _____
A/C & Phone _____
Business Address _____
A/C & Phone _____
Name, address, and telephone of person(s) to be contacted if patient cannot be located _____
A/C & Phone _____
Relationship to Patient _____
Name, address, and telephone of alternate person(s) to be contacted if patient cannot be located _____
A/C & Phone _____
Relationship to Patient _____

2. Physician(s) and Hospital:
Name _____
Office Address _____
A/C & Phone _____

3. Radioisotope Powered Pacer Information:
Serial No. _____ Date of Implant _____
Placement: subcutaneous/submuscular/intramuscular/other
right/left pectoral/abdominal/other
existing/new pocket
Stimulation rate: with Magnet _____ without _____
Threshold measurements: voltage _____ current _____ pulse width _____
other method (describe): _____
Equipment used to measure threshold _____

4. Previous Implant Information: Yes No If yes:
Manufacturer _____ Model _____ Date of implant _____
Why removed _____
Total number of previous implants _____

5. Lead: Manufacturer _____ Model No. _____
Serial No. (for new leads only) _____ Date of implant _____
Placement: Myocardial: right/left ventricle
transthoracic/transmediastinal
Endocardial: vein used _____
Previous leads (if applicable and available):
Myocardial: Number, models, and implant dates; how many removed?
Endocardial: Number, models, and implant dates; how many removed?

6. Clinical data:
Patient's age _____ Sex _____ Race _____ Height _____
Weight _____ Right handed/Left handed
Etiology of arrhythmia _____
Kind of arrhythmia _____
Previous drug therapy for arrhythmia _____
Associated diseases _____
Temporary pacing (for initial implants only) Yes No
Anesthetics used during surgery _____
Antibiotics: locally/systemically/none
Cortisones or other anti-inflamatory drugs: locally/systemically/none
Was pocket drained: Yes No If yes, how long? _____
Did complications or adverse reactions occur in pacemaker/lead surgery? ___
If yes, treatment _____
Comments _____

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION 1 Fee Exempt

1. APPLICATION ATTACHED

Applicant/Licensee: Norwalk Hospital

Application Dated: 11/30/84

Control No.: 03220

License No.: SNM-1504

2. FEE ATTACHED

Amount: 0

Check No.: 0

3. COMMENTS

Signed Brenda P. Latchuk

Date 12/13/84

12/31/84

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: EX 7C - no fee due

2. Correct Fee Paid. Application may be processed for:

Amendment _____

Renewal ✓

License _____

Signed Frances Brown

Date 12/24/84

12/24/84

REGION I FORM 213
(MARCH 1983)