



Medtronic

Standard Letter

CRM Technical Services U.S.
Mounds View, MN
Brady (800) 505-4636
Tachy (800) 723-4636
Instruments (800) 638-1991

DEATH AND PRODUCT HANDLING

Rev. B.1, 03-FEB-2009, Page 1 of 2

PACEMAKER (IPG – IMPLANTABLE PULSE GENERATOR)

DEFIBRILLATOR (ICD – IMPLANTABLE CARDIOVERTER DEFIBRILLATOR)

1. What should be done with an IPG or ICD after death?

- Nothing needs to be done to the IPG
- Program ICD detection and patient alert OFF

2. Is the IPG or ICD removed after death?

In many cases, the pacemaker or defibrillator is removed after death. The physician or hospital may request permission to remove the IPG or ICD for analysis purposes. The mortician may also request permission to remove the unit if the body is to be cremated.

3. How is the IPG or ICD removed?

- **IPG** – A small incision is made over the pacemaker implant site. The pacemaker is externalized and the lead (possibly two or three) is cut or disconnected from the pacemaker. The lead has a metal conductor and can be easily cut with an appropriate tool or instrument. The lead is generally left in place. The lead is connected to the pacemaker by small (usually No. 2) setscrews. Small Allen wrenches are used to loosen the setscrews that are concealed beneath a silicone rubber seal in the connector portion of the pacemaker.
- **ICD** – First, the detection and therapy capabilities of the ICD must be turned off using a Medtronic programmer to avoid a potentially hazardous shock to the mortician. Then, an incision is made over the ICD implant site. The ICD is externalized and the lead or leads are cut or disconnected from the ICD. The lead has a metal conductor and can be easily cut with an appropriate tool or instrument. The lead is generally left in place. The lead is connected to the ICD by small (usually No. 2) setscrews. Small Allen wrenches are used to loosen the setscrews that are concealed beneath a silicone rubber seal in the connector portion of the ICD.

DEATH AND PRODUCT HANDLING

Rev. B.1, 03-FEB-2009, Page 2 of 2

4. What is done with the ICD or IPG after removal?

After removal, we request that a Medtronic IPG or ICD be sent back to the Minneapolis Medtronic facility for analysis of electrical parameters and other factors. Contact your District Office to request a "Return Mailer for Explanted Product."

5. Can a removed pacemaker be reimplanted in another patient?

No. U.S. Federal Law prohibits reimplantation into another human being. An IPG or ICD that has been contaminated in any way with blood or body fluid of one individual should not be implanted in another individual. It is impossible to guarantee removal of body fluid or tissue from the device. Resterilization does not preclude the possibility of a reaction occurring.

6. Do morticians remove IPGs or ICDs?

Yes. In some cases morticians do remove IPGs or ICDs. Here again, the mortician should have the permission of the family of the deceased before removing the unit. The mortician may, however, leave the IPG or ICD in place with no particular difficulty for the normal preparation of the body for embalming.

7. Should IPGs or ICDs be removed before cremation?

Yes. We recommend that IPGs and ICDs be removed prior to cremation. Because of the nature of the sealing technique associated with ICDs and IPGs, considerable pressure will build up within the metal housing of the unit causing it to rupture forcefully.

8. Are pacemakers and defibrillators automatically removed and returned to the factory?

The removal of an IPG or ICD is still the prerogative of the family of the deceased. In situations where there is concern over the function of the device, the attending physician may recommend or suggest that removal take place in order to determine whether it is operating properly. Contact your District Office to request a "Return Mailer for Explanted Product."

9. What is the procedure for nuclear pacemakers?

Medtronic no longer markets the Model 9000 nuclear-powered pacemaker; however, Model 9000 is occasionally encountered at explant. A physician should explant the nuclear-powered generator from a deceased patient before the body is transferred to a mortuary. All explanted Model 9000 generators must be returned to Medtronic observing the handling procedures set forth by the Nuclear Regulatory Commission in licenses to implanting hospitals and manufacturers.

Please contact Medtronic Cardiac Rhythm Management Technical Services if you have any further questions.