

Pace4Life

Reuse / Recycling of Pacemakers

A guideline to funeral directors and associated parties

Authors

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Executive Summary

About us

Pace4Life is a Charity that promotes the collection and re-use of pacemakers for people in the developing world

Historically, the need for pacemakers has been neglected in the developing world, due to cost and the inaccessibility to healthcare. Pace4Life is committed to changing this, by:

- Raising public awareness that pacemakers can save and dramatically improve the quality of life of a person and the lives of their dependents
- Providing information, support and advocacy for people requiring pacemakers.
- Creating an active community of patients willing to stand up, be heard and donate their used pacemakers.

Our Mission

Our mission is to make a lasting impact in the health and well being of people in developing countries by reusing pacemakers which are currently thrown away as waste.

To achieve this we aim to run a range of projects and services that fall broadly into five areas:

- Information
- Advocacy
- Procurement
- Awareness raising
- Research

Additionally, firmly believing in the principle of patient-centered medicine we are committed to increasing the employment opportunities at Pace4Life for people with pacemakers and also encouraging them to become volunteers.

The history of Pace4Life:

- Provide pacemakers to the underprivileged people in the developing world.

The idea for Pace4Life came out of a chance conversation with a mortuary technician who mentioned that the cupboards in her lab were being cluttered up with discarded pacemakers. Currently, pacemakers removed prior to cremation are not reused/recycled and either thrown away or dumped into boxes and stock piled over years laying waste in funeral parlors and mortuaries across the country.

Pace4Life is the only charity devoted to reusing discarded pacemakers to save lives in the developing world

Detailed Overview

The purpose of this project is to create a central organization that obtains pacemakers for evaluation and subsequent sterilization, creating a distribution network for safe reuse.

“Reuse” can give millions of people worldwide the opportunity to save lives in developing nations using a currently wasted resource: the tiny pacemakers that help regulate heartbeat.

Our goal to create a scalable model that can be replicated across the world for the benefit of developing nations and for those unable to afford pacemakers and the associated therapy.

“The prevalence of cardiovascular disease is expected to increase 137 percent between 1990 and 2020 for those living in low- and middle- income countries, authors write. It's estimated that as many as 1 million people worldwide die annually from slow heart rates.” - ScienceDaily (Oct. 9, 2009)

History / Background

In the United Kingdom, approximately 35,000 individuals undergo pacemaker implant surgery each year, costing around £5,000 - £10,000 a time. When a pacemaker user dies, the device is buried with them, or, if the deceased chooses to be cremated it is discarded either as medical waste or often just placed in a box and forgotten. In the developing world around 2 million people die every year due to inaccessibility to medical healthcare and the prohibitive cost of lifesaving devices and a pacemaker surgery.

In the 21st century, the healthcare disparities between the industrialized world and those in under-developed countries have become all too apparent with cardiovascular disease having an increasing impact on death rates. Innovative methods of delivering normally costly healthcare to impoverished countries are required.

Pace4Life is responding to this situation by undertaking a project that will see thousands of discarded pacemakers sent to needy individuals, using creative methods of delivering costly healthcare to impoverished countries. Instead of the wasteful practice of binning pacemakers, Pace4Life is seeking to establish a process whereby people/patients donate old pacemakers to Pace4Life to be tested, and either reused or recycled.

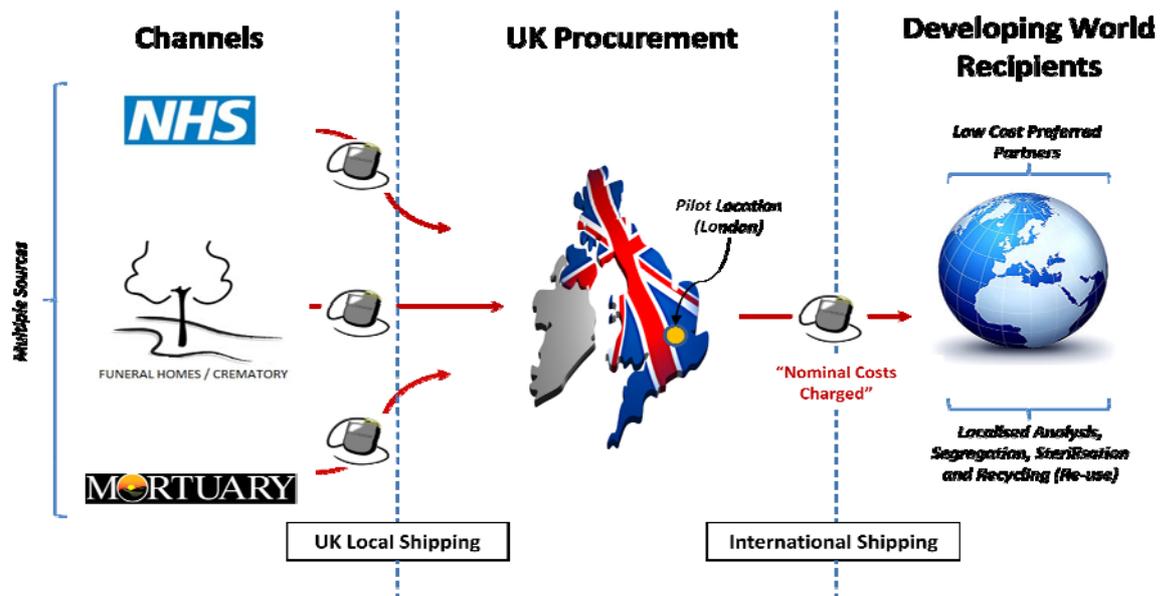
“Some foreign manufacturers have reduced the cost of pacemakers to as little as \$800, a price that still makes it out of reach in poor nations. Despite the substantial cost reduction, a new pacemaker is often more than the annual income of the average worker in underdeveloped nations,” - Kim A. Eagle, M.D., Cardiologist and a director of the U-M Cardiovascular Center.

Approach

Pace4Life proposes to create an initial link between the Developed world and the Developing world by facilitating the collection of used pacemakers from Hospitals, Funeral Homes/Crematoriums and Mortuaries. Pace4Life will assess the pacemakers viability for reuse or require recycling, facilitating this as required.

By partnering with other charitable organisations locally and in the developing world, Pace4Life propose Ghana and Pakistan as ideal pilot countries due to already established links, relationships and Letters of Consent obtained from their respective Ministries of Health. Overtime Pace4Life will look to refine the model and widen the audience to other countries and patient recipients.

The long term aim is to streamline the process, reducing overheads (shipping, procurement, analysis, refurbishment and sterilisation) and increasing funding through donations and the mining of pacemakers for valuable minerals/metals.



Frequently Asked Questions

- ***Who are the partners?***

We are developing our links with established teaching hospitals across the world, medical charities globally and in addition working alongside the NHS, MHRA and other supporting organisations. We aim to create a series of hubs that will be responsible for the collection and shipping of pacemaker devices.

- ***Have pacemakers been reused previously?***

Yes. The proof of concept has been well established. The organisation "Heart to Heart" in the US has been collecting and distributing used pacemakers for second use in the developing world since 1994. Pace4Life aims to use a similar principle for the UK market.
<http://www.theheart.org/article/995109.do>

- ***Is the reuse of pacemakers safe?***

There is a growing body of scientific publications that support the claim that pacemaker devices can be reused after appropriate sterilisation and functionality checks. The University of Michigan is currently undertaking a large-scale clinical study with the FDA to obtain regulatory approval for the refitting of used pacemakers in the US.
<http://www2.med.umich.edu/prmc/media/newsroom/details.cfm?ID=1592>

- ***Where do we get the pacemakers from?***

Pacemaker devices are currently removed in hospitals, mortuaries and funeral homes when the remains of the deceased are prepared for cremation or burial. We seek to encourage these organisations to send us the used pacemakers instead of discarding them. Via obtaining Patient Consent, NHS support and Legal and Regulatory abidance we seek to make this idea real.

- ***What is the average life-span of a pacemaker?***

Pacemakers are powered by long-lasting lithium batteries and usually encased in either stainless steel or titanium. Once fitted the average life-span of a pacemaker is between 7 -10 years. We will look to use pacemakers with =>70% battery life in line with the protocol set and used by the University of Michigan.

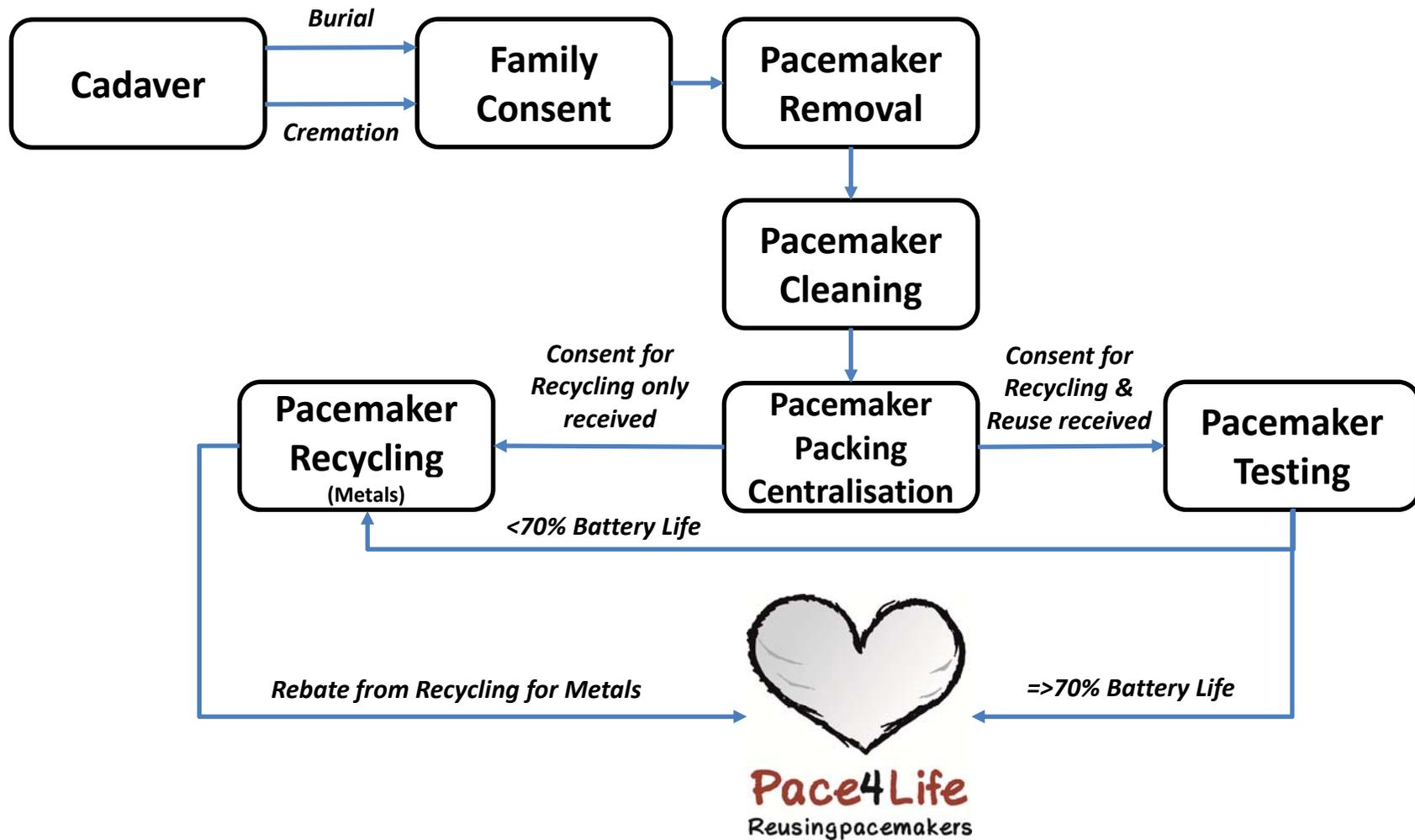
- ***How will patient data be kept safe?***

Pacemaker and their data will be refurbished prior to any reuse, in the process all patient data will be erased with new pacemaker leads purchased ready for reuse.



Pacemaker - Process Overview

Pacemaker Reuse - Process Overview





Pacemaker Recovery & Decontamination

Pacemaker Recovery & Decontamination Process

The steps below outline the Procedure for the Post-mortem Removal of Pacemakers (performed at funeral homes or crematories):

1. Pacemakers are easy to remove. The majority of devices are implanted in the upper left thoracic region just under the skin.
2. Palpate the area where the device is located and make an incision just above the device.
3. Dissect the device out using blunt dissection with angular haemostats, being careful not to scratch or damage the device.
4. After blunt dissection, using your fingers carefully pull device from chest area until the leads are just attached to the pacemaker.
5. Once leads are away from the remains, cut the silastic covering and lead connections approximately 4-5 centimetres from its connections using blunt tip scissors.
6. Wash the device thoroughly with warm water and soap.
7. Rinse and wipe down with a quality quaternary ammonium disinfectant or Sodium peroxide disinfectant (Accord® solution, Lysol etc.).
8. Place the device in an envelope with the completed pacemaker donation form.
9. Ensure each pacemaker is bagged separately with its parent donation form.
10. Store in storage bins provided or suitable other storage ready for collection at agreed date/time.



Pacemaker Donation

Pacemaker Donation Form
Pace4Life

Every year up to 2 million people die in the developing world because they don't have enough money for a lifesaving pacemaker operation.

In the United Kingdom over 35,000 individuals undergo pacemaker implant surgery each year, costing around £5,000 - £15,000 at a time. When a pacemaker wearer passes away, the device is buried with them, or, if the deceased chooses to be cremated, it is removed before cremation and then discarded as medical waste. Yet in the developing world, approximately 2 million people die every year due to the prohibitive cost of these lifesaving devices and associated surgery.

In the 21st century, the disparities in healthcare between the industrialised world and those in under-developed countries have become all too apparent, with cardiovascular disease having an increasing impact on death rates.

Pace4Life is responding to this situation by undertaking a project that will see discarded pacemakers sent to needy individuals, delivering vital healthcare to impoverished countries. Instead of the current practice of discarding pacemakers, Pace4Life is seeking to establish a process whereby families donate discarded pacemakers to Pace4Life to be reused or recycled.

If you or your loved one has a pacemaker, you may be able to help save lives simply by donating that device to Pace4Life.

If you agree to donate the device, please complete and sign this form in full. The pacemaker will be respectfully removed at a hospital, mortuary or funeral parlour and the device sent to Pace4Life.

*If you have any questions at all about Pace4Life please do not hesitate to contact:
Mr Balasundaram Lavan (Pace4Life) - lavan@pace4life.org / www.pace4life.org*

Your wishes regarding the donation of a pacemaker

Details	Pacemaker Patient	Next of Kin
First Name(s)		
Last Name(s)		
Address		
Contact Number		
Email Address		
Date of Birth		
Date of Death (if applicable)		
Relationship to Pacemaker Patient		

INSTRUCTIONS ON HOW TO FILL THIS FORM AND FOLLOWING SECTIONS
Pace4Life

1. Show your agreement to the relevant sections by "TICKING" the relevant boxes.
2. If you do not agree please leave the box(es) blank.
3. Please sign and date the form accordingly
4. Please populate the details of the donated pacemaker so that we can match the pacemaker to the completed donor form.

PLEASE BE ASSURED THAT YOU OR YOUR LOVED ONE WILL BE TREATED WITH CARE AND RESPECT.

Section 1: Instances of Cremation: You or your loved one's decision about the donation of a pacemaker that will be removed prior to cremation.

Where you or your loved one is to be cremated, the pacemaker will be removed prior to cremation. This is because pacemakers are a fire hazard during cremation and are liable to explode.

If you agree to the donation of the pacemaker that has been or will be removed before the funeral, please tick this box.

I/We agree to donate the pacemaker removed prior to cremation and its reuse/re-implantation/recycling.

Section 2: Instances of Burial: You or your loved one's decision about the removal and donation of a pacemaker to be removed before a burial

Where you or your loved one is to be buried, the pacemaker will not be automatically removed. With your agreement, the pacemaker will be removed typically at a hospital, mortuary or funeral parlour prior to burial.

If you agree to the pacemaker being removed before burial please tick this box

I/We agree to the pacemaker being removed before burial and its reuse/re-implantation/recycling.

Section 3: Overall Consent & Understanding

All of my/our questions about donating a pacemaker have been answered.

Patient / Next of Kin Name
Signature Date

Donated Pacemaker Details
Pace4Life

Pacemaker Make	Pacemaker Model	Pacemaker Serial No



Gift Aid



Pace4Life
Reusingpacemakers

giftaid it

Gift Aid declaration – single donations

Name of Charity: **Pace4Life**

Please treat the enclosed gift of £ ----- as a Gift Aid donation.

I confirm I have paid or will pay an amount of Income Tax and/or Capital Gains Tax for the current tax year (6 April to 5 April) that is at least equal to the amount of tax that all the charities and Community Amateur Sports Clubs (CASCs) that I donate to will reclaim on my gifts for the current tax year. I understand that other taxes such as VAT and Council Tax do not qualify. I understand the charity will reclaim 25p of tax on every £1 that I have given.

Donor's details

Title ----- First name or initial(s) -----

Surname -----

Full Home address -----

Postcode -----

Date -----

Signature -----

Please notify the charity or CASC if you:

- *Want to cancel this declaration*
- *Change your name or home address*
- *No longer pay sufficient tax on your income and/or capital gains.*

If you pay Income Tax at the higher or additional rate and want to receive the additional tax relief due to you, you must include all your Gift Aid donations on your Self Assessment tax return or ask HM Revenue and Customs to adjust your tax code.



Pace4Life
Reusingpacemakers

giftaid it

Gift Aid declaration – for past, present & future donations

Name of Charity: **Pace4Life**

Please treat as Gift Aid donations all qualifying gifts of money made

today in the past 4 years in the future

Please tick all boxes you wish to apply.

I confirm I have paid or will pay an amount of Income Tax and/or Capital Gains Tax for each tax year (6 April to 5 April) that is at least equal to the amount of tax that all the charities or Community Amateur Sports Clubs (CASCs) that I donate to will reclaim on my gifts for that tax year. I understand that other taxes such as VAT and Council Tax do not qualify. I understand the charity will reclaim 25p of tax on every £1 that I gave up to 5 April 2013 and will reclaim 25p of tax on every £1 that I give on or after 6 April 2013.

Donor's details

Title ----- First name or initial(s) -----

Surname -----

Full home address -----

Postcode -----

Date -----

Signature -----

Please notify the charity or CASC if you:

- *Want to cancel this declaration*
- *Change your name or home address*
- *No longer pay sufficient tax on your income and/or capital gains.*

If you pay Income Tax at the higher or additional rate and want to receive the additional tax relief due to you, you must include all your Gift Aid donations on your Self Assessment tax return or ask HM Revenue and Customs to adjust your tax code.



NHS Guidance



DEPARTMENT OF HEALTH AND SOCIAL SECURITY

To: Regional Health Authorities)
 District Health Authorities)
 Special Health Authorities for London) for action
 Post-Graduate Teaching Hospitals)
 Boards of Governors)

Community Health Councils - for information

March 1983

HEALTH SERVICES MANAGEMENT OWNERSHIP OF IMPLANTS AND
 REMOVAL OF CARDIAC PACEMAKERS AFTER DEATH

SUMMARY

This notice gives guidance on ownership of implants and removal of cardiac pacemakers after the patient's death.

DEFINITION

1. An implant is any device or prosthesis implanted surgically in and intended to remain within the patient's body.
2. While intra-uterine devices and dental crowns and fillings are implants, they are unlikely to give rise to the problems with which this notice deals.

OWNERSHIP OF IMPLANTS

3. On implantation, an implant becomes the property of the person in whom it has been implanted and it remains his or her property even if it is subsequently removed. Following the patient's death, it forms part of his or her estate unless there is any specific provision to the contrary.
4. An implant is rarely removed during a patient's life unless it has failed and is to be replaced; in such cases the consultant may wish to have the implant examined to establish the reason for its failure. In general, it is neither necessary nor desirable that implants should be removed after the patient's death, except in the case of cardiac pacemakers (see paragraph 8 below).
5. In view of the possibility of dispute about the right of the health authority or consultant to retain an implant removed for examination or replacement, a revised form of consent for operation has been agreed with the Joint-Co-ordinating Committee of the Medical Defence Union, the Medical Protection Society and the Medical and Dental Defence Union of Scotland.

THE REVISED FORM OF CONSENT FOR OPERATION

6. The revised form of consent for operation is attached. It includes an acknowledgement that any implant supplied to and implanted in the patient is supplied subject to the condition that if it is subsequently removed for examination or replacement the ownership will vest in the health authority by or on behalf of whom it is removed. The purpose of this part of the form is to enable the health authority, without seeking specific consent subsequently, to retain the implant after removal, to conduct any tests on it to establish the cause of failure or to see how it has functioned or could be improved, and to dispose of the implant as they see fit when it has been examined. If the patient has not signed the acknowledgement before the implantation, it will be necessary to obtain specific consent to retention of the implant if it is subsequently removed.
7. The revised form is intended for use in orthopaedic, cardiac and other specialised departments where implants are used. The existing form should continue to be used in other departments.

CARDIAC PACEMAKERS - REMOVAL AFTER DEATH

8. Where a patient fitted with a cardiac pacemaker has died it is desirable for the pacemaker to be removed and returned to the cardiac department which implanted it for checking and evaluation of its performance so that the knowledge gained can be applied for the benefit of future patients. If the patient is to be cremated it is also *essential* that the pacemaker should first be removed since if heated to high temperature, pacemakers are liable to explode and give off toxic fumes and could be hazardous to cremation staff or premises.

9. If the patient dies in hospital, removal of the pacemaker will normally be carried out by a mortuary technician, unless for clinical reasons a hospital doctor decides to remove it himself. However very many patients with pacemakers are likely to die outside hospital. It has now been accepted that in such cases, pacemakers may be removed or caused to be removed by funeral directors, who have been advised accordingly by the Home Office through the National Association of Funeral Directors.

10. Funeral directors have also been asked to contact the cardiac department at the hospital which implanted the pacemaker (where this is known or can be ascertained) to find out the local arrangements for receiving pacemakers for examination. Where it is not possible to establish the hospital which implanted the pacemaker, the nearest cardiac department should be contacted. It is understood that the removal of the pacemaker is normally undertaken as part of the preparation of the body for cremation or burial. Any additional fee which may be requested by the funeral director for the removal should be met by the health authority, in whom ownership of the implant will then rest. In all cases the consent of the person lawfully entitled to dispose of the body should be obtained before the pacemaker is removed.

ACTION

11. Authorities are asked to bring this Notice to the attention of those concerned and are recommended to adopt the new form of consent for operation, in place of the present form HMR 10, in orthopaedic, cardiac and other departments where implants are used. Authorities should also consider with cardiac units the arrangements for recovery of pacemakers from patients who die at home and for payment of funeral directors' fees.

From:

Health Service Division 2A
Hannibal House
Elephant and Castle
LONDON SE1 6TE

Tel: 01 703 6380

Further copies of this Notice may be obtained from DHSS Store, Health Publications Unit, No 2 Site, Manchester Road, Heywood, Lancs OL10 2PZ quoting code and serial number appearing at top right-hand corner.

FOR USE IN ORTHOPAEDIC, CARDIAC AND OTHER DEPARTMENTS WHERE IMPLANTS ARE USED

FRONT HOSPITAL

CONSENT FOR OPERATION† UNIT NO

I of

..... hereby consent to

*[the submission of my * (child (ward to]

under go the operation of

the nature and purpose of which have been explained to me by

Dr/Mr*

I also consent to such further or alternative operative measures as may be found necessary during the course of the above-mentioned operation and to the administration of general, local or other anaesthetics for any of these purposes.

I acknowledge and agree that any implant supplied to and implanted in me as part of this operation or the further or alternative operative measures mentioned above, is supplied and implanted subject to the condition that if at any time it is removed by or on behalf of a health authority:

- (a) for the purpose of replacement, or
- (b) where a replacement is not required, to enable it to be examined, or
- (c) where in the case of a cardiac pacemaker paragraph (a) or (b) does not apply, after my death

the ownership of the implant will vest in that health authority.

No assurance has been given to me that the operation will be performed by any particular practitioner.

Date Signed (Patient/Parent/Guardian)*

I confirm that I have explained the nature and purpose of this operation to the patient/parent/guardian*

Date Signed (Medical/Dental* Practitioner)

ANY DELETIONS, INSERTIONS OR AMENDMENTS TO THE FORM ARE TO BE MADE BEFORE THE EXPLANATION IS GIVEN AND THE FORM SUBMITTED FOR SIGNATURE.

†THIS FORM IS NOT SUITABLE FOR CONSENT TO PROCEDURES SUCH AS ELECTROPLEXY, STERILISATION OR VASECTOMY.

*Delete as necessary

BACK UNIT No

 SURNAME
 (Block letters)

 FIRST NAMES

 ADDRESS

 POSTCODE