Pakistan Society of Interventional Cardiology

Guidelines to Reuse Of Cardiovascular Catheters And Devices In Pakistan

A policy document by Pakistan Society of Interventional Cardiology

Writing committee:

M Hafizullah, Nadir Khan, Nadeem Rizvi, Azhar M Kiani

Introduction:

All over the world clinicians try to provide cost effective health care, more so in resource constraint situations. At times single use devices are used again for the benefit of patients. Closely monitored single use device (SUD) reprocessing provides an opportunity to save costs and may have the potential for a favorable impact on environmental waste. SUD needs to be cleaned, sterilized and re-packaged ensuring that the quality and performance is not compromised and the device remains safe and effective for clinical reuse.

Most developing countries utilize in hospital facilities for cleaning, resterilisation and packaging, as they do not have any third-party reprocessors. Concerns have been raised at different forums regarding the reuse of SUD and expired cath lab equipment and it was felt necessary in the

last meeting of Pakistan Society of Interventional Cardiology, held in Rawalpindi Institute of Cardiology to develop a consensus document regarding the need and method of reuse of cardiovascular products, especially coronary and vascular catheters, valvuloplasty balloons, electrophysiology catheters and pacemakers and defibrillators. Hence an expert writing committee was formed to give its recommendations for the approval of the Pakistan Society of Interventional Cardiology. This document intends to develop and propose guidelines to help clinicians, hospitals and government agencies in this context and moreover suggests standard operating procedures for reuse.

This document shall address the following aspects:

1. Definition of a single use device
2. Why should we reuse catheters/devices in cardiology in Pakistan?
3. Potential concerns - why should we not reuse?
4. Are there any ethical and legal issues?
5. Do we need informed consent for reuse of SUD?
6. Is there a need for Government oversight? International and National perspective
7. Reuse of SUDs and expired devices in Cardiology in Pakistan
8. Protocols recommended for reuse
9. What is further needed in Pakistan?

1. Definition of a single use device?

A SUD is a device that is recommended for use once i.e. in only one patient for a single procedure. Such devices are not intended by the manufacturers to be disassembled, cleaned, reassembled, and reused, since doing so may jeopardize its physical and/or chemical integrity, performance, safety, and effectiveness.[1] The responsibility of designating a device as single use lies solely with the manufacturer and there is no statutory requirement by the manufacturer to provide validation to support its designation as single-use.

2. Why should we reuse catheters/devices in cardiology in Pakistan?

All over the world SUDs have been reused for a long time.[2,3] This is an important and cumbersome process that involves cleaning, disassembly as required, disinfection, reassembling, inspection, function testing, re-packing, sterilization and relabeling to ensure that a medical device can safely be reused. This includes SUDs that have been previously used in a patient, opened but not used and also those that have crossed their expiry date.

Reuse achieves three goals: save costs of a procedure especially in resources constrained environments, utilize devices which are not available in the inventory for any reason, and utilize necessary devices that are not available in the country. Annual estimates of healthcare industry savings with reprocessing in US have been reported to be approximately $ 1.8 billion per year.[4] A survey conducted across 3000 hospitals using reprocessed SUDs in USA reported savings in excess of $ 150 million every year.[5] Cost estimate studies from Germany report savings of up to 20 million Euros per year from reprocessing balloon angioplasty catheters.[6] Apart from saving cost, reuse can also lead to reduce toxic biodegradable waste, which needs to be disposed off properly which in turn will have a positive effect on environment. Reprocessing is listed as a best practice for its environmental benefits and as a top green purchasing practice.[7]

In Pakistan certain cardiovascular products have been reused all over the country, essentially to reduce the costs and utilize newer devices after the expired date, which are not yet available in Pakistan. Broadly the cardiovascular materials that are reused or used after expired date can be categorized to coronary and vascular catheters and guide wires, balloon valvuloplasty catheters, electrophysiology catheters, pacemakers and defibrillators.

a) **Coronary and vascular catheters and guide wires:** They used to be reused by some hospitals, however overall reduction in the cost and difficulty is assuring complete disinfection of these luminal catheters has resulted in discontinuation of this trend except for special circumstances like certain devices that are rarely required and used and some that are not yet available in Pakistan but needed in certain essential and life saving procedures.

b) **Balloon valvuloplasty catheters:** These are used to perform percutaneous balloon mitral valvuloplasty (BMV) in rheumatic valvular heart disease, a scourge of millions of socio-economically disadvantaged patients in Pakistan. Balloon catheters are also used in congenital heart diseases such as pulmonary and aortic valve stenosis. Percutaneous Transvenous Mitral Commissurotomy (PTMC) is a potentially life-saving procedure that is performed most frequently in poor segment of society with rheumatic mitral valve stenosis. It is one of the most commonly performed interventional procedures. Each year a large number of patients in Pakistan undergo PTMC with most of these procedures performed in public hospitals. The cost of PTMC varies from *free* to a maximum payment of Rs 300,000. PTMC catheter along with its accessories approximately costs Rs 1,60,000. Taking into account the other SUDs used in the procedure the total hardware costs for this life-saving procedure would be in excess of Rs 1,80,000. The subsidy in cost is only possible if the valvuloplasty catheter is reused at least three times. Ethylene oxide (ETO) sterilization has withstood the test of time as an effective sterilization technique and there have been no adverse events reported in literature (not withstanding the under reporting of such events). A "No reuse policy" for such procedures would be detrimental to vast majority of patients. Majority of the patients in Pakistan will not afford the cost of new balloon valvuloplasty catheter and hence will not be a candidate for this life saving treatment.

c) **Electrophysiology catheters:** The catheters and equipment are inherently very expensive and if new catheters are used for all cases the cost will become prohibitive. Many electrophysiology (EP) laboratories all over the world reuse catheters. In USA reprocessing EP and imaging catheters have reported savings of up to $150,000.[5] EP catheters are manufactured to be durable enough to be reused in excess of five times with maintained effectiveness for cardiac pacing and recording of electrical signals. These catheters are being reused in Pakistan as well. The reuse policy in ablation procedures has also helped in shortening the procedure time with the flexibility of using multiple catheters which best suit the need of a given patient.

d) **Pacemakers/defibrillators** – The cost of pacemakers and defibrillators is prohibitive and most patients pay the cost out of their own pocket. These cardiac implantable electronic devices (CIED) are implanted in only 25 per million population in developing countries as opposed to 300 per million implants in the western world.[8,9] This data can be extrapolated for the Pakistani population because of a large number of patients in our country cannot afford these devices. To bridge this gap, in Pakistan, CIEDs have been rarely explanted and reused in exceptional circumstances when a patient dies soon after receiving the device or develops problem with the device, re-sterilization of PPMs or ICDs after the expiry date of sterilization or utilizing CEID procured from abroad which are intact but expiry date of sterilization has passed. Saving precious lives with this reuse practice in Pakistan has also been acknowledged in Western published literature, which promotes and facilitates this practice.[10]

3. Potential concerns regarding why should we not reuse?

What are the potential concerns that determine the reuse or otherwise of the devices? Firstly, potential risk of cross contamination and transmission of infections; secondly, inadequate cleaning, leaving residues created from chemical agents during sterilization leading to endotoxic reactions; thirdly, loss of functional integrity resulting in device failure; and fourthly, legal and ethical issues.

What is the evidence regarding reuse of SUDs? The data about the frequency of adverse patient events related to reuse of SUDs is limited internationally and scarce nationally. It is often under-reported and there is a possibility that validation of the different steps in reuse cycle is not regularly performed. At times even *new* SUDs can cause injuries, infections or malfunction. Currently available appropriate sterilization techniques effectively destroy all types of infectious bacteria and key viruses (including HIV and hepatitis C). Testing the devices for mechanical integrity prior to reuse ensures that the risk of malfunction is minimized. Several clinical studies of reuse of SUDs including electrophysiology (EP) catheters, angioplasty balloons, single-use endoscopic instruments etc. have established their relative safety without increasing patient risk of infections or pyrogenic reactions. [11-13]

The current evidence supports that SUDs reused or reused after expired date after proper sterilization following proper SOPs meeting FDA requirements are safe and effective. The overall safety record for reprocessed SUDs has been excellent. The Center for Disease Control (CDC) endorses that reprocessing of SUDs, which can be properly cleaned and sterilized, does not pose a risk to patients. It is recommended that a device should not be reprocessed and reused if, it cannot be cleaned adequately, if sterility of a reprocessed device cannot be safely demonstrated and importantly if integrity, functionality and safety of a reprocessed SUD cannot be demonstrated to be equal to the original device specifications

4. Are there any ethical and legal issues?

Technically reprocessing and/or reuse of a SUD is like a "remanufacture" and inherently the original manufacturer is no longer responsible for the performance and safety of the device. Therefore, the person or hospital who reprocesses or reuses a device intended by the manufacturer for use on a single occasion has to bear full responsibility for its safety and effectiveness. Hospitals reprocessing single-use devices need to assume full liability and responsibility for the device's safety and efficacy.

5. Do we need informed consent for reuse of SUD?

A never-ending debate continues over the issue of obtaining informed consent from the patients on whom the reprocessed item has to be used. Undoubtedly patients have a right to know and health care personnel should not be reluctant to disclose information about reuse and reprocessing of SUDs. It is indeed a challenge to explain to the patient details related to cleaning, sterilizing and reusing devices without perhaps unnecessarily scaring them. There is a risk that informed patients may also feel that they are receiving a lower standard of care. On the other hand properly reprocessed devices (reused or after expiry date) are reported to be as safe as new ones and are being used in the interest of patients with full conviction of the physician regarding its sterility and functionality. Whether it is mandatory to disclose to patients that it was reprocessed, often remains an unsettled issue between the hospital and the patient.[14,15] Routinely all over the world, physicians often do not obtain consent for reuse because they genuinely believe that reuse is not associated with substantive risk. According to the North America Society of Pacing and Electrophysiology 2000 guideline, if the use of reprocessed EP devices is not associated with material and functional risk, then there is no

ethical reason why this issue must be added to the long list of risks known to be associated with the procedure.[16]

If there is a choice between a new SUD, SUD after expiry date and reused SUD then SUD should be preferred if there are no economic restraints. But if the choice is between no treatment and resued SUD or SUD after expiry date then it may be discussed with the patients openly and recorded especially in case of reused PPM and ICDS or CRT device.

6. Is there a need for Government oversight? International and National perspective

A manufacturer labels device as single-use only, as it believes that it could not be safely and reliably used more than once. Another reason may be because the manufacturer choses not to conduct the studies needed to demonstrate that the device can be labeled as reusable.[17] It is convenient for a manufacturer to seek approval to market a device as single use, as the regulators do not require them to show that reusing it would be inappropriate or hazardous. Since the FDA can only evaluate a device for its intended use by the manufacturer, if a device is approved as SUD, it only implies it can be used safely and reliably once. It does not however denote that it cannot be used safely and reliably more than once, if appropriately reprocessed. Manufacturers often change labels on medical devices from reusable to single use, sometimes without any significant change in design, performance or material that would preclude safe reuse. Such a shift in labeling surprisingly does not require approval from the FDA; which in fact does not even mandate any device to carry a single use label.[18]

There has been a growing apprehension in the minds of health care personnel that this over-enthusiasm on part of original equipment manufacturers to market devices as single-use when they could just as well be reusable was driven by economic incentives. Occasionally, many manufacturers of SUDs themselves offered their own recycling and reprocessing programs, further questioning the relevance of “single use” designation and necessity of complying with it. At the same time, rising cost of medical devices, often force hospitals to reprocessing so as to bring down expenditure incurred to patients.

Food and Drug Administration (FDA) in 1999 sought feedback from healthcare professionals, device manufacturers and reprocessing firms to determine if federal oversight was needed to address the issue of

reprocessing. The United States Government Accountability Office (GAO) was asked to review the practice of SUD reprocessing in US hospitals. The GAO report entitled "Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted" was submitted in June 2000.[19] The salient features of the report were: Approximately 20–30% of US hospitals confirmed reuse of at least one type of SUD and one-third of the hospitals had operational contracts with third-party reprocessors. It is also likely that some hospitals, which reprocess SUDs, do not actually report that they did so.

The report stated that to successfully reprocess a device that has been used previously, health care facilities should stringently follow the following standard steps: cleaning, refurbishing, sterilization and inspection of functional integrity

The GAO mentioned that reprocessors or institutions may need to establish limits on the maximum number of times a device can be reused. The GAO report concluded that while SUDs reprocessing may theoretically pose health risks, clinical evidence shows that careful reprocessing of appropriate SUDs did not pose a risk to patient health. However, it was also clear that some SUDs could not be safely reprocessed, that procedures for safe reprocessing were not always followed, and that SUD reprocessing needed monitoring.

Subsequently, US FDA developed strict regulations to monitor reprocessing and assure quality-controlled evaluation whereby hospitals and third-party reprocessors of SUDs are subject to the stringent regulations. This ensured that the reprocessed SUDs is safe and effective.[20-22]

In the developing world, reuse is common due to scarcity of medical supplies and shortage of financial resources. There are no third-party reprocessors in most developing countries including Pakistan, therefore in-house reprocessing is done in most hospitals. A survey across 26 coronary angioplasty centers, which had been practicing reuse, was conducted in 1997 in India. Most centers had a hospital infection control committee and the most frequent agents used for sterilization were ethylene oxide (90%) and glutaraldehyde (73%). No special consent was obtained from patients prior to reuse in the majority of centers. In its draft guidelines related to reuse, the committee recommended that reuse of disposables should be allowed to continue with strict adherence to norms for sterilization.[23] All equipment for reuse should be tested for functional and mechanical integrity. The date of sterilization should be clearly mentioned on the package and any sterilized

equipment that is not used within 6 months, should be re-sterilized before use.

7: **Reuse of SUDs in Cardiology in Pakistan**

Many studies have reported reprocessing and reuse of coronary angioplasty balloon catheters,[24-27] diagnostic and radiofrequency ablation EP catheters [28-31] and pacemakers and implantable devices to be safe and cost effective. [32-35]

a. Reuse of devices in percutaneous coronary interventions (PCI): PCI catheters are hollow lumened so in reprocessing both sterility and mechanical issues need to be addressed. Cleaning, disinfecting and sterilizing these luminal catheters are not foolproof. Mechanical performance is sometimes jeopardized with reports of failure to cross tight coronary lesions, longer procedure times and use of higher volume of contrast[24] With increase in use of these catheters, the overall cost has reduced and routinely balloon catheters may not be resterilized and reused. However balloons with expired sterilization date and those opened but never used may be resterilized and reused.

Most of the devices used in cardiology are considered expired because of loss of sterility. Device (Balloon catheters/ stents/angioplasty wires/catheters) function is not affected by expiry date. Hence if a device is used after proper ETO sterilization, it will not affect patient safety, efficacy or outcomes. However it is recommended that it should be monitored by hospital committee on sterilization and proper resterilization protocols and techniques should be strictly followed. Resterilization date should be clearly mentioned on the package and if not used in 6 months it should be resterilized. Integrity and function of the device should be checked by the physician before using it.

b. Reuse of Balloon valvuloplasty catheters: To make this procedure available for poor patients balloon catheters can be reused following stringent cleansing measures, disinfecting steps and sterilization process however not more than three times. Any adverse events with the reuse, infection, and failure of balloon to expand should be reported, audited and the reprocessing methods reviewed.

c. Reuse of Electrophysiology catheters: Electrical, physical and mechanical characteristics of RF ablation catheters, have been reported to be safe with reuse.[27,28] Data on newer deflectable EP catheters and comparisons of

performance characteristics between new and reprocessed EP catheters also confirmed that reprocessed catheters are functionally equivalent to new catheters up to five uses/reprocessing cycles, meeting all industry standards and regulatory requirements.[27,31,36]

d. Reuse of pacemakers/defibrillators: Due to cost constraints and most patients' dependence on out-of-pocket expenses, access to pacemakers, implantable cardioverter-defibrillators (ICD) and biventricular devices (collectively labeled as CIED – cardiac implantable electronic device) is limited in the developing world. It is estimated that in the low income countries, nearly 1 million individuals die annually due to lack of access to pacemakers.[37]Hence reuse of explanted CIED is in great demand in poor countries with constrained resources. Current generation pacemakers have long battery life that often exceeds that of the patients who receive them. It makes explants and reuse of these devices a feasible option. ICDs can also be potentially reused following patient death since most modern ICDs have a battery life of 6–10 years, and median survival time after ICD implantation in patients above 75 years is about 5 years. [38.39]

There are different resources for CIED, like they are available after explantation because of patient deaths, donation of the explanted devices from different organizations, and devices that are not used after their shelf life has expired but intact battery life. For new devices the approximate shelf life is estimated to be between 12 and 18 months, after which it is considered expired due to loss of sterility.[33]

Pacemakers should only be considered for reuse if the previous clinical record has been reliable, without any documented malfunction, and it has an adequate remaining life – often arbitrarily set at more than 4–5 years or cutoff of more than 70% battery life.[34,35] Reuse should be avoided if there is an external loss of integrity or when the device has been recovered from a patient who has died suddenly (since in such cases device malfunction cannot be ruled out with certainty). Device leads should not be reused due to difficulty in ensuring sterility and mechanical integrity.

Properly resterilized devices have been reported to be safe for reuse. Various studies have shown no increased risk of infection, mortality or difference in safety/efficacy/ outcomes following reuse as compared to new device implantations. [34,35,41,42] Reuse of properly sterilized ICDs (with more than 3 years of estimated remaining battery life) has been reported to be associated with delivery of appropriate therapy and no increased risk of infections or

device failure.32 In a recent 6 month outcome analysis of patients who underwent implantation of a new or reused pacemaker, ICD, CRT device in 5 years (n = 887 of which 260 devices were reused) no difference in rate of infection, device malfunction or device related death was observed as compared to those with a new device.[34] A meta-analysis of 18 studies (n = 2270 patients) with reused devices reported an infection rate of 1.97% and device malfunction rate of 0.68%, highlighting the safety profile of these devices.[42] It is important to be careful while extracting the devices since damage to set screws during extraction is an important cause of future increased risk of device malfunction.

Consent is required prior to death for device removal. The Heart Rhythm Society (HRS) guidelines recommend that physicians should seek patient's consent for post-mortem device retrieval while they are alive.[43] Studies have shown that most (70–80%) of patients with devices and the general public were willing to give consent to device removal for charitable reuse in the under-privileged countries.[44] Confidential health information are also often deleted from device memory prior to donation for reuse. The North American Society of Pacing and Electrophysiology Policy Conference in a statement endorsed the reuse of pacemakers and concluded that it is not a risk factor for device infection.[45] The 2002 American College of Cardiology/American Heart Association/NASPE guidelines also acknowledged that pacemaker reuse "may eventually add significantly to the cost-effectiveness of cardiac pacing".[46]

Hence properly cleansed, sterilized, and reliably tested devices for function and battery life are safe and effective way to not only help save lives but also improve quality of life in disadvantaged nations. It is strongly recommended that legal and government restrictions to procure such devices needs to be facilitated and standards of care should be developed to ensure delivery of healthcare resources to patients with insufficient personal resources and/or inadequate health insurance.

8: Protocols recommended for reuse

For solid catheters (non-luminal)

a) To start, verify that the catheter can still be reused - (maximum 5 times)
b) The catheter should be soaked in an enzymatic detergent
c) Entire surface of the catheter should be meticulously cleaned, using flush and brush if required.

d) Rinse well in potable tap water/sterile distilled water.
e) Immerse in any high level disinfectant, which has material compatibility such as 3% hydrogen peroxide solution for 3 hours.
f) Rinse with clean water thoroughly, multiple times and wipe dry.
g) Use alcohol flush to facilitate drying. The device should be completely dry for the ethylene oxide sterilization to be effective
h) Inspect for any blood stains or dirt and discard if present
i) Recheck for integrity and functionality
j) Re-package in double layers
k) Sterilize with ethylene oxide and label the date of re-sterilization
m) Note the reuse number (different color code for 1st, 2nd, 3rd, 4th & 5th final reuse)

For hollow (luminal) equipment

a) To start, verify that the catheter can still be reused - (maximum 3 times)
b) Soak the catheter in an enzymatic detergent (neutral or alkaline)/enzymatic cleaning agent. Ensure that the lumens are completely filled with enzymatic detergent and disinfectant.
c) Meticulously clean the entire surface of the catheter, using flush and brush if required. Rinse with pressurized potable tap water/sterile distilled water for 10 min.
e) Immerse in any high level disinfectant, which has material compatibility such as 3% hydrogen peroxide solution for 3 h.
f) Rinse with clean water thoroughly, multiple times and wipe dry.
g) Drying to be performed by using compressed air jets free of oil, dust and moisture.
h) Inspect for any blood stains or dirt and discard if present.
i) Recheck for integrity and functionality of the catheter.
j) Re-package in double layers
k) Sterilize with ethylene oxide and label the date of re-sterilization
m) Note the reuse number (different color code for 1st, 2nd and 3rd reuse)

For pulse generators/defibrillators

a) Inspect for integrity and clean outer surface with tap water

b) Unscrew lead and clean inner lumen with syringe and needle followed by flushing

c) Cleanse the device with an enzymatic detergent (neutral or alkaline)/enzymatic cleaning agent.

d) Dry at room temperature for 24 h or use compressed air

e) Check and record all parameters before sterilization

f) Immerse in any high level disinfectant which has material compatibility such as povidone-iodine for 4 h

g) Clean with sterile distilled water, wipe with 70% ethanol and dry with compressed air

j) Repackage in double layers and sterilize using ethylene oxide

l) Label the date of re-sterilization

m) Consider resterilizing with ethylene oxide 2–3 days prior to implant

n) For all ethylene oxide re-sterilization:, aerate for 24 h before use

p) Always check for sterility indicator and ensure use within expiry date of resterilization

r) Check for mechanical integrity and functionality of device testing before reuse

(I) What is further needed in Pakistan?

I. All specialties inclusive of cardiology reusing SUD should **formulate guidelines and standard operating procedures** for reuse. These guidelines should include the list of items that can be reused, the number of recommended reuses, the procedure for reuse and validating effectiveness of reprocessing procedures, to ensure sterility and intact functionality of these devices and ensure quality control. An adverse event record should be maintained for all reused devices and there should be a periodic review and audit.

II. Standard and validated written protocols should be followed by all hospitals for reprocessing for every type of SUD. There should be a periodic review and audit of the protocols and adherence to protocols.

III. It is strongly recommended that every hospital should have a **reprocess/reuse committee** consisting of end user - doctors, infection control officers, microbiologists, nurses and administrators which should oversee central reprocessing, infection control, biomedical engineering and cost accounting.

This in-house committee should be responsible and accountable for the protocol and safety issues. The hospital should provide adequate space for reuse, trained personnel and other consumables that are required.

IV. **Third party reprocessing** units should be encouraged and need to be stringently regulated and be accountable for quality control.

V. Importantly, the reused catheters/devices should not be billed to the patient, as the reuse policy is primarily to reduce the cost. The cost of sterilization process should be accounted for in the catheterization laboratory charges and should not exceed 10% of the original cost of the catheters. Reused CIEDs should not be charged however implantation expenses may be charged.

VI. Every endeavor should be made by the societies (PCS and PSIC) to minimize the price of all medical devices. This should be done with the help of government agencies. Sealing the maximum retail price (MRP) based on the landing price with a well-defined formula for different medical SUD should be established.

References:

1. Knox A. NHS Dumfries & Galloway; 2010. Guidelines on Single Use Devices.http://www.nhsdg.scot.nhs.uk/dumfries/files/2.05%20Guidelines%20on%20Single%20Use%20Devices.pdf
2. Belkin N.L. Reuse of single-use devices. AORN J.2001;74(1):15.
3. Hussain M., Balsara K.P., Nagral S. Reuse of single-use devices: looking back, looking forward. Natl Med J India. 2012;25(3):151–155.
4. Landro L. Hospitals reuse medical devices to lower costs. Wall Street J. 2008;(March (19)) http://online.wsj.com/article/SB120588469924246975.html
5. Moduga A. Reduce, reuse, recycle: reprocessing medical devices. Hosp Manage. 2010 http://www.hospitalmanagement.net/features/feature80981/
6. Ischinger T.A., Neubauer G., Ujlaky R., Schätzl H., Bock M. Reuse of single use medical devices after quality assured reprocessing: hygienic, legal and economic aspects. Potential for cost savings in interventional cardiology. Z Kardiol. 2002;91(11):889–898.
7. Association of Peri-Operative Registered Nurses (AORN) 2006. Supra Note 38, Position Statement Environmental Responsibility (March)

8. Shenthar J., Bohra S., Jetley V. A survey of cardiac implantable electronic device implantation in India: by Indian Society of Electrocardiology and Indian Heart Rhythm Society. Indian Heart J. 2016;68(1):68–71.
9. Seidl K., Senges J. Worldwide utilisation of implantable cardioverter/defibrillators now and in the future. Card Electrophysiol Rev. 2003;7:5–13.
10. Kantharia B.K., Patel S.S., Kulkarni G. Reuse of explanted permanent pacemakers donated by funeral homes. Am J Cardiol. 2012;109(January (2)):238–240.
11. Frank U., Herz L., Daschner F.D. Infection risk of cardiac catheterization and arterial angiography with single and multiple use disposable catheters. Clin Cardiol. 1988;11(11):785–787.
12. Cohen J., Haber G.B., Kortan P. A prospective study of the repeated use of sterilized papillotomes and retrieval baskets for ERCP: quality and cost analysis. Gastrointest Endosc. 1997;45(2):122–127.
13. Gensini G.G. Institute for Health Policy Analysis. Reuse of Disposable Medical Devices in the 1980.Georgetown University Medical Center; Washington (DC): 1984. Reuse in angiography, cardiac catheterization, and pacing: summary and recommendations; pp. 139–141.
14. Macpherson C. An ethical imperative to use reprocessed medical equipment. Acad Med. 2010;85(9):1397. [author reply 1397]
15. Kwakye G., Pronovost P.J., Makary M.A. Commentary: a call to go green in health care by reprocessing medical equipment. Acad Med. 2010;85(3):398–400.
16. Lindsay B.D., Kutalek S.P., Cannom D.S. Reprocessing of electrophysiology catheters: clinical studies, regulations, and recommendations. A report of the NASPE Task Force on Reprocessing of Electrophysiological Catheters. North American Society of Pacing and Electrophysiology. Pacing Clin Electrophysiol. 2001;8(Pt. 1):1297–1305.
17. U.S. Government Accountability Office. GAO-08-147, Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk. www.gao.gov/new.items/d08147.pdf.
18. Siranosian K. 2010. Many Hospitals Now Safely Reuse ‘Single Use’ Medical Devices.http://www.triplepundit.com/2010/03/reuse-single-use-medical-devices
19. GAO United States Government Accountability Office . United States General Accounting Office; Washington DC: 2000. Report to Congressional Requesters. Single-Use Medical Devices: Little Available Evidence of Harm

from Reuse, but Oversight Warranted http://www.gao.gov/new.items/he00123.pdf 05.
20. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health . 2008. Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107172.pdf
21. Carungi R.S., Simon I.S. 2010. Safety and Performance Evaluation of Remanufactured Harmonic.http://www.amdr.org/wp-content/uploads/2010/09/White-Paper-Safety-and-Performance-Eval-of-Remfd-Harmonic-Scalpels.pdf
22. Food and Drug Administration. Executive Summary Survey on the Reuse and Reprocessing of Single-use Devices (SUDs) in US Hospitals. http://http//www.fda.gov/MedicalDevices/DeviceRegulationandGuidanceReprocessingofSingle-UseDevices/ucm121678.htm.
23. US Government Accountability Office . 2008. Report to the Committee on Oversight and Government Reform, House of Representatives: Reprocessed Single-Use Medical Devices.http//www.gao.gov/new.items/d08147.pdf [January]
24. Plante S., Strauss B.H., Goulet G., Watson R.K., Chisholm R.J. Reuse of balloon catheters for coronary angioplasty: a potential cost-saving strategy? J Am Coll Cardiol. 1994;24(6):1475–1481.
25. Rozenman Y., Gilon D., Zelingher J. One-stage coronary angiography and angioplasty. Am J Cardiol. 1995;75(1):30–33.
26. Mak K.H., Eisenberg M.J., Plante S., Strauss B.H., Arheart K.L., Topol E.J. Absence of increased in-hospital complications with reused balloon catheters. Am J Cardiol. 1996;78(September (6)):717–719.
27. Avitall B., Khan M., Krum D., Jazayeri M., Hare J. Repeated use of ablation catheters: a prospective study. J Am Coll Cardiol. 1993;22(5):1367–1372.
28. Ferrell M., Wolf C.E., 2nd, Ellenbogen K.A., Wood M.A., Clemo H.F., Gilligan D.M. Ethylene oxide on electrophysiology catheters following resterilization: implications for catheter reuse. Am J Cardiol. 1997;80(12):1558–1561.
29. Bathina M.N., Mickelsen S., Brooks C., Jaramillo J., Hepton T., Kusumoto F.M. Safety and efficacy of hydrogen peroxide plasma sterilization for repeated use of electrophysiology catheters. J Am Coll Cardiol. 1998;32(5):1384–1388.

30. Mickelsen S., Mickelsen C., MacIndoe C. Trends and patterns in electrophysiologic and ablation catheter reuse in the United States. Am J Cardiol. 2001;87(3):351–353. A9.
31. Lester B.R., Alexander A.A., Miller K., Boser N.P., Sullivan B.F., Brucker G.G. Comparison of performance characteristics between new and reprocessed electrophysiology catheters. J Interv Card Electrophysiol. 2006;17(2):77–83.
32. Pavri B.B., Lokhandwala Y., Kulkarni G.V., Shah M., Kantharia B.K., Mascarenhas D.A. Reuse of explanted, resterilized implantable cardioverter-defibrillators: a cohort study. Ann Intern Med. 2012;157(8):542–548.
33. Kirkpatrick J.N., Papini C., Baman T.S. Reuse of pacemakers and defibrillators in developing countries: logistical, legal, and ethical barriers and solutions. Heart Rhythm. 2010;7(11):1623–1627
34. Baman T.S., Kirkpatrick J.N., Romero J. Pacemaker reuse: an initiative to alleviate the burden of symptomatic bradyarrhythmia in impoverished nations around the world. Circulation. 2010;122(16):1649–1656.
35. Balachander J. Efficacy and safety of refurbished pacemakers—report on collaborative programme with 140 implantations and 6-year follow up. Indian Heart J. 1989;41:430.
36. Aton E.A., Murray P., Fraser V., Conaway L., Cain M.E. Safety of reusing cardiac electrophysiology catheters. Am J Cardiol. 1994;74(11):1173–1175.
37. 2009. Heartbeat International.http://www.heartbeatintl.org/mission.htm
38. Pellegrini C.N., Lee K., Olgin J.E. Impact of advanced age on survival in patients with implantable cardioverter defibrillators. Europace. 2008;10(11):1296–1301.
39. Pavri B.B., Lokhandwala Y., Kulkarni G.V., Shah M., Kantharia B.K., Mascarenhas D.A. Reuse of explanted, resterilized implantable cardioverter-defibrillators: a cohort study. Ann Intern Med. 2012;157(8):542–548.
40. Kirkpatrick J.N., Papini C., Baman T.S. Reuse of pacemakers and defibrillators in developing countries: logistical, legal, and ethical barriers and solutions. Heart Rhythm. 2010;7(11):1623–1627
41. Rosengarten M.D., Portnoy D., Chiu R.C., Paterson A.K. Reuse of permanent cardiac pacemakers. Can Med Assoc J. 1985;133(4):279–283.
42. Baman T.S., Kirkpatrick J.N., Romero J. Pacemaker reuse: an initiative to alleviate the burden of symptomatic bradyarrhythmia in impoverished nations around the world. Circulation. 2010;122(16):1649–1656.
43. Carlson M.D., Wilkoff B.L., Maisel W.H. Recommendations from the heart rhythm Society Task force on device performance policies and guidelines endorsed by the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) and the international coalition of

pacing and electrophysiology organizations (COPE) Heart Rhythm. 2006;3(October (10)):1250–1273.
44. Lange D.C., Kirkpatrick J.N., Oral H., Goldman E.B., Eagle K.A., Baman T.S. Post-mortem cardiac device retrieval for re-use in third world nations: views of the general public and patient population. Heart Rhythm 30th Annual Scientific Sessions; May 14th, Boston, Mass.; 2009. pp. AB20–AB24.
45. Boal B.H., Escher D.J., Furman S. Report of the policy conference on pacemaker re-use sponsored by the North American Society of Pacing and Electrophysiology. Pacing Clin Electrophysiol. 1985;8(2):161–163.
46. Gregoratos G., Abrams J., Epstein A.E. ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices—summary article: a report of the American College of Cardiology/American Heart Association task force on practice guidelines (ACC/AHA/NASPE committee to update the 1998 pacemaker guidelines) J Am Coll Cardiol. 2002;40(9):1703–1719.