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Guidance on reuse of cardio-vascular catheters and devices in India: A consensus document

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ABSTRACT

Reuse of medical device is accepted worldwide. Benefits of reuse include not only cost saving but a favorable impact on environment. However, certain requirements should be met for reuse to be safe and effective. The devices, which can be reused, should be clearly defined, a meticulous process for disinfection and sterilization followed and its functionality ascertained before use. Further, an appropriate consent should be obtained where necessary and the cost saving entailed should be directly passed on to the patient.

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1. Preamble

Healthcare providers all over the world, particularly in low resource settings are expected to deliver quality patient care in a cost effective manner. Closely monitored and regulated single use device (SUD) reprocessing provides an opportunity to do so along with the potential to have a favorable impact on environmental waste. Devices can be sterilized **onsite** (in-hospital) or by **third-party reprocessing facilities** which enter into contracts with hospitals. In the west, hospitals often engage with third-party reprocessors who clean, sterilize and re-package SUDs in a manner that the quality and performance are not affected and the SUD remains safe and effective for clinical reuse, eliminating any legal liability on the hospital.

In the developing nations of Africa, Asia, Eastern Europe, Central America, and South America, although reuse is very common, cleaning and sterilization of SUDs is often performed within the hospital, sometimes in an unregulated manner. India has no third-party reprocessors and up-to-date national policies on reuse. Hence an expert writing committee was formed to give its recommendations regarding the need and method of reuse of

cardiovascular products, especially coronary and vascular catheters, valvuloplasty balloons, electrophysiology catheters and pacemakers/defibrillators. This document intends to facilitate a dialogue with governmental health agencies and the medical community to frame appropriate guidelines and in the interim help clinicians and hospitals to follow standard operating procedures for reuse.

This document shall cover the following points:

- A. What is a single use device?
- B. Why reuse catheters/devices in cardiology in India?
- C. Need for Government oversight of SUD reprocessing: International and National perspective
- D. Potential concerns associated with reuse
- E. Ethical and Legal issues related to reuse
- F. Informed Consent
- G. Reuse in Cardiology in India
- H. Protocols recommended for reuse
- I. What is further needed in India?

(A) What is a single-use device? A SUD is a medical 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,

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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.

(B) Why reuse catheters/devices in cardiology in India?

World-over hospitals have been reusing SUDs since 1970s.^{2,3} Reprocessing a medical device 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 and also those that have crossed their expiry date.

Cost saving on medical expenditure is the single most important reason for reprocessing of SUDs. 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 cost savings, reuse can also lead to *reduction in the toxic-biodegradable waste* generated by disposing medical devices thus favorably affecting the environmental footprint of hospitals. Reprocessing is listed as a best practice for its environmental benefits and as a top green purchasing practice.⁷

Cardiovascular products in India have also been reused with the sole consideration of reducing the cost. Broadly the cardiovascular materials that are reused can be categorized to coronary and vascular catheters and guide wires, balloon valvuloplasty catheters, electrophysiology catheters, pacemakers and defibrillators.

Coronary and vascular catheters and guide wires – have been traditionally reused by majority of the hospitals in India. However the overall reduction in the cost of these materials over the past few years and the difficulty is assuring complete disinfection of these luminal catheters have raised the question of the necessity to reuse them in the present day.

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 deprived patients in India. They are also used in congenital heart diseases such as pulmonary and aortic valve stenosis. Balloon Mitral Valvuloplasty is a potentially life-saving procedure that is performed most frequently in the economically weaker sections with rheumatic mitral valve stenosis. It is one of the most commonly performed interventional procedures. Each year about 10,000 patients in India undergo BMV with most of these procedures performed in public hospitals. The cost of BMV varies from free to a maximum reimbursement of Rs 60,000 (the approximate cost of BMV in a governmental hospital varies from Rs 15,000 to Rs 30,000). In the state of Maharashtra, the government health scheme sanctions a meager Rs 20,000 for the BMV procedure, thereby presupposing that there would be reuse of SUDs, this is because the cost of the BMV catheter along with its accessories is approximately Rs 1,00,000. 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 1,20,000. This subsidy in cost is only possible because the valvuloplasty catheter is reused for at least three times. Ethylene oxide sterilization has withstood the test of time as an effective sterilization technique and there have been no adverse events reported in literature (notwithstanding the under reporting of such events). A “No reuse policy” for such procedures would be detrimental to vast majority of Indian patients. Majority of the patients will not afford the cost of new balloon valvuloplasty catheter and hence not opt for this life saving treatment. In case the reimbursing agencies were to pay for the new hardware for every

individual patient, there will be a three-fold increase in the budget allocation.

Electrophysiology catheters – reprocessing is adopted by many electrophysiology (EP) laboratories in the US with the dual purpose of reducing costs and lessening the environmental impact from discarded bio-waste. Reprocessing EP and imaging catheters have reported savings up to \$150,000.⁵ Catheters were found 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 India as well. The cost of ablation procedure by conventional technique in India varies from Rs 15,000/- in government-aided hospitals to Rs 75,000/- in re-implemented or private hospitals. However, with a “No reuse policy” the cost of these ‘single use’ catheters and hardware would be about Rs 1,00,000/- for every procedure. Additionally there would be the cost of the electrophysiology equipment, catheterization laboratory charges, hospital stay and professional fees. 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.

Pacemakers/defibrillators – The bradycardia pacemakers cost varies from Rs 60,000/- to Rs 1.5 lakhs; the implantable intracardiac defibrillators (ICD) cost from 2 lakhs to 5 lakhs, the bi-ventricular pacemakers from 2.5 to 7 lakhs (COMBO devices) in India. This cost is prohibitive to many Indians and there is no uniform policy of re-imbursement. Thus, these cardiac implantable electronic devices (CIED) are implanted in only 25 per million population in India as opposed to 300 per million implants in the western world.^{8,9} To bridge this gap, in India CIEDs have been reused. Saving precious lives with this reuse practice in India has also been acknowledged in Western published literature, which promotes and facilitates this practice.¹⁰

(C) Need for Government oversight of SUD reprocessing?

A device is labeled as single-use only by the manufacturer, as the latter believes that it could not be safely and reliably used more than once, *or because the manufacturer chooses not to conduct the studies needed to demonstrate that the device can be labeled as reusable.*¹¹ Moreover when a manufacturer seeks approval to market a device as single use, 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 imply 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.¹²

Hence there was a **growing apprehension** in the minds of health care personnel that this over-enthusiasm on part of original equipment manufacturers (OEM) 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 forced hospitals to reprocessing so as to bring down expenditure incurred to patients.

FDA oversight of SUD reprocessing in USA: Noting the increasing trend of unregulated reuse, the 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 2000.¹³ 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. However, currently in the cardiovascular products – apart from EP catheters, most hospitals in US and the western world follow a no reuse policy.
 - 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
 - Inspection of functional integrity
 - Sterilization
- Although not addressed directly by the report, the GAO also mentioned that reprocessors or institutions may need to establish limits on the maximum number of times a device can be reused and discard it when that threshold is reached.
- **The GAO report concluded** that while SUD device 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.^{14–16} This ensured that the reprocessed SUD is safe and effective.

An additional US GAO report in 2008, also concluded that the available evidence indicated no additional health risk from reprocessed SUDs.¹⁷ Currently, the Reprocessing of Devices Marketed by Manufacturers as “Single Use” is Lawful Under the **Federal Food, Drug, and Cosmetic Act (FDCA)** and reprocessors are considered to be “manufacturers”. A reprocessed device that meets all the requisite requirements of the FDCA act is lawful and may be marketed legally in the United States.

Data from outside USA:

- **Canada:** Surveys across Canadian hospitals report that approximately 25% of health care facilities reprocessed SUDs.¹⁸ Although initially most health care facilities (85%) in Canada reprocessed SUDs using in-house units, due to change in policies which disallowed in-house reprocessing, this is now increasingly being done by commercial third-party reprocessors. **In 2014, MEDEC, the Canadian association for the medical technology industry**, advocated for federal regulatory oversight for reprocessed SUDs resulting in bringing the commercial reprocessing of SUDs under its regulatory framework.
- **Europe:** The practice of reprocessing SUDs is not presently regulated at the level of the European Union (EU) resulting in heterogeneous practices throughout Europe. The extent of reuse in hospitals is estimated to be 10% in the UK, 30% in Denmark and 100% in Norway.¹⁹ While in France, Spain, and Switzerland reuse of SUDs is illegal, UK authorities have issued guidelines regarding potential risks and consequences of reusing SUDs in an

unregulated manner.²⁰ The Department of Health, Germany is the only European authority which has allowed reuse, subject to special regulations since 1998. The most recent Directive 2007/47/EC assigned the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), to prepare a report on the “Safety of Reprocessed Medical Devices Marketed for Single-Use”.²¹ The SCENIHR committee considered reuse a potential option and noted that *the possibility for safe reprocessing is dependent on the material used and geometry of the device*. It is hence very important that the entire reprocessing technique as well as the functional integrity of the device be adequately evaluated and validated.

- **Australia:** The Therapeutic Goods Administration introduced regulations in 2003 for reprocessors of SUDs legislating them to conform to the same standards as OEM’s and to demonstrate that reprocessed SUDs were as safe and perform as well as the original device.²²

Reuse scenario in the developing world: In the developing world, reuse is very common due to paucity of medical supplies and shortage of financial resources.

Indian scenario: There are no third-party reprocessors in India, however in-house reprocessing is done in most hospitals across India. A survey across 26 coronary angioplasty centers, which had been practicing reuse, was conducted in 1997 under the aegis of the Cardiological Society of India (CSI). 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 **The 1997 CSI report** recommended that 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.

It is advisable that the governmental agencies in India lay down norms for reuse and the reprocessing units be screened and approved periodically to ensure safety and efficacy of reused devices.

(D) Potential concerns associated with reuse:

- Inadequate cleaning and/or residues created from chemical agents during sterilization leading to endotoxic reactions
- Risk of cross contamination and transmission of infections
- Device failure with loss of functional integrity
- Legal and ethical issues

Disinfection is defined as a process that eliminates potential pathogens. Sterilization on the other hand renders an object free from all viable microorganisms including bacterial spores.

Data about the frequency of adverse patient events related to reprocessing of SUDs is often under-reported and limited and validation of the different steps in reuse cycle is not regularly performed. It is important to realize that even new SUDs can lead to patient injuries or infections or malfunction. 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.^{24–27}

Therefore current evidence indicates that SUDs reprocessed in accordance with FDA requirements are safe and effective and the

overall safety record for reprocessed SUDs is excellent. The 2008 GAO report also concluded that there was no causative link between reported injuries or deaths and reprocessed SUDs. The Center for Disease Control (CDC) also endorses the viewpoint 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
- If integrity, functionality and safety of a reprocessed SUD cannot be demonstrated to be equal to the original device specifications

(E) Ethical and legal issues:

Reprocessing and/or reuse of a SUD are considered a “remanufacture” and therefore the original manufacturer is no longer responsible for the performance and safety of the device. Anyone who reprocesses or reuses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness. Hospitals reprocessing single-use devices need to assume full liability and responsibility for the devices safety and efficacy.

(F) Consent:

There has been long standing debate over the issue of obtaining informed consent from the patients on whom the reprocessed item has to be used. Although patients do have a right to know and health care personnel should not be reluctant to disclose information about reuse and reprocessing of SUDs, it is often an ethical challenge to explain to the patients issues related to cleaning, sterilizing and reusing devices without perhaps unnecessarily scaring them. Informed patients may also feel that they are receiving a lower standard of care. Moreover since properly reprocessed devices are reported to be as safe as new ones whether it is mandatory to disclose to patients that it was reprocessed, often remains an unsettled issue between the hospital and the patient.^{28,29} Physicians often do not routinely obtain consent for reuse because they perceive 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.³⁰

- Patients should be informed if they directly ask about the hospital's policy and they are well within their rights to request that reprocessed catheter not be used.
- It should be the decision of the treating physician to include this discussion when informed consent is obtained. If a patients objects to reuse, then it is obviously essential to use new equipment in them.

In the Indian context, with the current regulatory and clinical environment it may be advisable to obtain an informed consent before reusing cardiovascular catheters and consent is mandatory before implanting reused pacemakers/defibrillators.

(G) Reuse in Cardiology:

Various studies have reported reprocessing and reuse of coronary angioplasty balloon catheters,^{31–38} diagnostic and radio-frequency ablation EP catheters^{39–46} and pacemakers and implantable devices to be safe and cost effective.^{10,47–58}

(G.1) Reuse of devices in percutaneous coronary interventions (PCI): The practice of reprocessing and reusing PCI balloon catheters is presently not common in the West. While using reprocessed PCI catheters (which are hollow lumened), *both sterility and mechanical issues* need to be addressed. Cleaning, disinfecting and sterilizing these luminal catheters are not

foolproof. Also, mechanical performance is sometimes jeopardized with reports of failure to cross tight coronary lesions, longer procedure times and use of higher volume of contrast.³⁴ With increase in use of these catheters, the overall cost has reduced and this has promoted a no reuse policy in many hospitals in India. However those hospitals choosing to reuse these catheters need to ensure safety, both in terms of sterilization and performance, not reuse luminal catheter more than three times and finally, since the intended reason for reuse is to reduce the cost, they should not be charged.

(G.2) Reuse of Balloon valvuloplasty catheters: If stringent cleansing measures, disinfecting steps and sterilization process is followed, these catheters can be reused, 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.

(G.3) Reuse of Electrophysiology catheters: Electrical, physical and mechanical characteristics of RF ablation catheters, has also been reported to be safe with reuse.^{40,41} Data on newer deflectable EP catheters and comparisons of performance characteristics between new and reprocessed EP catheters also confirmed that reprocessed catheters were functionally equivalent to new catheters up to five uses/reprocessing cycles, meeting all industry standards and regulatory requirements.^{40,45,46} Reprocessed Soundstar 3D ultrasound mapping catheters have also been shown to be functionally equivalent to original devices in terms of accuracy of image registration and mechanical performance. Therefore one time use of these catheters appears to be an unnecessary and expensive policy, especially in India.

(G.4) Reuse of pacemakers/defibrillators: While access to pacemakers, implantable cardioverter-defibrillators (ICD) and biventricular devices (collectively labeled as CIED – cardiac implantable electronic device) is widespread in the developed world, many patients in the developing world are unable to receive these devices due to cost constraints. It is estimated that in the low income countries, nearly 1 million individuals die annually due to lack of access to pacemakers.⁵⁹ Hence reuse of explanted CIED is of immense public health potential in countries with poor healthcare resources. Given the long battery life of current generation pacemakers, their “life-span” often exceeds that of the patients who receive them, making 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.^{47,48} Since biventricular pacemakers are programmed to provide maximum pacing, their potential for reuse only exists if the device is acquired shortly after the original implant.

CIED are available after explantation because⁴⁹:

- Patient death – donation of the explanted devices from organizations like STIMUBANK and Heartbeat International, funeral homes and crematoriums are important sources for device reutilization.
- Device upgrade

Another source of reuse is when new devices are deemed “expired”. 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.

- **Which pacemakers to reuse and which not?:** 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.^{50,51} 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 are generally not reused due to difficulty in ensuring sterility and mechanical integrity.

- **What is the evidence for reuse of CIED?:** Properly re-sterilized 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.^{50–57} Kantharia et al. assessed the reuse of donated pacemakers (n = 121) from funeral homes in USA and implanted in patients at a charity hospital in Mumbai, India. Improved quality of life without any significant complications (infections or device malfunction/failures) was reported over a mean follow-up of 661 days.¹⁰ 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.⁴⁸ 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) at JIPMER, Puducherry, no difference in rate of infection, device malfunction or device related death was observed as compared to those with a new device.⁵⁸ 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.⁵¹ 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 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.⁶⁰ 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.⁶¹ 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.⁶² 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”.⁶³
- Hence devices, if properly cleansed, sterilized, and reliably tested for function and battery life represent a safe and effective way to not only help save lives but also improve quality of life in impoverished nations. 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 inadequate personal resources and/or inadequate health insurance.

(H) Suggested protocols for reuse in India:

- For solid catheters (non-luminal)
 - Based on number of reuses defined (maximum 5 times), verify that the catheter can still be reused.
- Soak the catheter in an enzymatic detergent (neutral or alkaline)/enzymatic cleaning agent.
- Meticulously clean the entire surface of the catheter. Use flush and brush if required. Discard the used enzymatic detergent.
- Rinse well in potable tap water/sterile distilled water.
- Immerse in any high level disinfectant, which has material compatibility such as 3% hydrogen peroxide solution for 3 hours.
- Rinse with clean water thoroughly, multiple times and wipe dry. Use alcohol flush to facilitate drying. The device should be

completely dry for the ethylene oxide sterilization to be effective and avoid producing toxic residues.

- Inspect for any blood stains or dirt and discard if present
- Check for integrity and functionality
- Re-package in double layers
- Sterilize with ethylene oxide
- Label the date of re-sterilization
- Note the reuse number (different color code for 1st, 2nd, 3rd, 4th & 5th final reuse)
- For hollow (luminal) equipment
 - Based on number of reuses defined (maximum 3 times), verify that the catheter can still be reused.
- 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.
- Meticulously clean the entire surface of the catheter. Use flush and brush if required. Discard the used enzymatic detergent.
- Rinse with pressurized potable tap water/sterile distilled water for 10 min.
- Immerse in any high level disinfectant, which has material compatibility such as 3% hydrogen peroxide solution for 3 h.
- Rinse with clean water thoroughly, multiple times and wipe dry.
- Drying to be performed by using compressed air jets free of oil, dust and moisture.
- Inspect for any blood stains or dirt and discard if present.
- Check for integrity and functionality of the catheter.
- Re-package in double layers
- Sterilize with ethylene oxide
- Label the date of re-sterilization
- Note the reuse number (different color code for 1st, 2nd and 3rd reuse)
- For pulse generators/defibrillators
 - Inspect for integrity and clean outer surface with tap water
- Unscrew lead and clean inner lumen with syringe and needle followed by flushing
- Cleanse the device with an enzymatic detergent (neutral or alkaline)/enzymatic cleaning agent.
- Dry at room temperature for 24 h or use compressed air
- Check parameters
- Immerse in any high level disinfectant which has material compatibility such as povidone-iodine for 4 h
- Clean with sterile distilled water
- Wipe with 70% ethanol
- Air-drying
- Repackage in double layers
- Sterilize using ethylene oxide
- Label the date of re-sterilization
- Consider re-sterilizing with ethylene oxide 2–3 days prior to implant
- For all ethylene oxide re-sterilization:
 - Aerate for 24 h before use
- Check for sterility indicator
- Use only within expiry date of re-sterilization
- Check for mechanical integrity, functionality & device testing before reuse

(I) What is needed in India?

- Each hospital should have its own reprocess/reuse committee consisting of doctors, infection control officers, microbiologists, nurses and administrators which should oversee central reprocessing, infection control, biomedical engineering and cost accounting.
- The in-house committee should take responsibility and be accountable for the protocol and safety issues. The hospital should provide adequate space for reuse, trained personnel and other consumables that are required.

- Standard and validated written protocols should be followed for reprocessing for each type of SUD. There should be a periodic review and audit.
- It is advisable that cardiology and other specialties reusing catheters formulate common 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.
- Third party reprocessing units should be encouraged and need to be stringently regulated and accountable for quality control.
- Importantly, the reused catheters/devices should not be billed to the patient as the reuse policy is primarily done to reduce the cost. The cost of sterilization process should be accounted for in the catheterization laboratory charges and or should not exceed 10% of the original cost of the catheters. Reused CIEDs should not be charged.
- Made or make in India concept for these SUD should be encouraged and facilitated to offset the cost, issues related to reuse and improve penetration of therapy.
- Engagement with the health regulatory authorities and price control for all imported medical devices should be addressed. Sealing the maximum retail price (MRP) based on the landing price with a well-defined formula for different medical SUD should be established.

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