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ASSESSMENT OF REUSE PRACTICES FOR SINGLE-USE MEDICAL DEVICES (SUDs) IN INDIA:

Aligning with Global Best Practices

A WHITE PAPER BY

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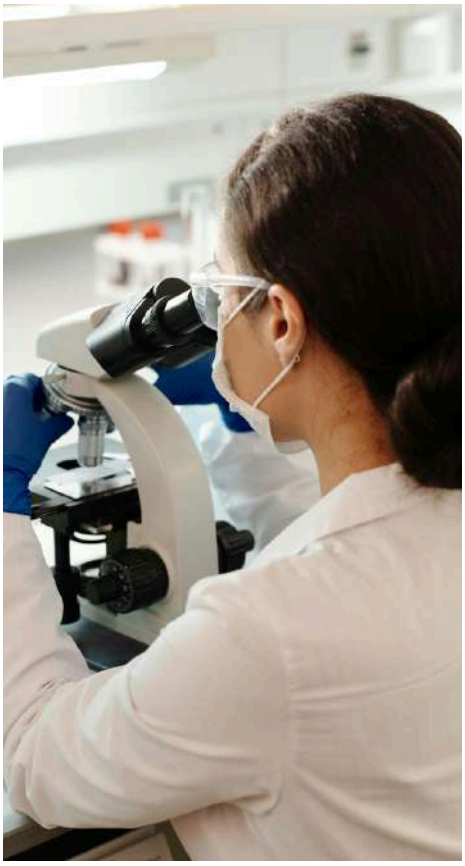
ACKNOWLDEGEMENT

We are pleased to present to you the white paper titled ***"Assessment of Reuse Practices for Single-Use Medical Devices (SUDs) in India: Aligning with Global Best Practices"***. This document is the culmination of months of rigorous research, stakeholder consultations, and expert insights, and reflects DakshamA Health's steadfast commitment to promoting patient safety and healthcare policy reform in India.

This white paper would not have been possible without the dedication and collaborative spirit of our entire team. We extend our heartfelt gratitude to the researchers, analysts, and project coordinators whose tireless efforts laid the foundation for this comprehensive analysis. Their work in identifying regulatory gaps, examining global best practices, and developing key recommendations has been instrumental in shaping this important advocacy tool.

We are deeply thankful to the patients who shared their lived experiences, bringing to light the urgent need for informed consent, ethical reuse protocols, and stronger regulatory oversight in India. Their voices have been vital in underscoring the human impact of policy decisions.



Furthermore, we gratefully acknowledge the valuable contributions of our distinguished webinar speakers, whose expertise enriched the dialogues that informed this paper- **Dr. Amit Vora**, Consultant, Cardiologist, Sir H. N. Reliance Foundation Hospital, **Mr. David Sheon**, Vice President, Strategic Initiatives and External Affairs, Association of medical device reprocessors (AMDR), **Ms. Sairekha Suresh**, Founder, T1D Foundation, **Advocate Narender Ahooja**, State Drugs Controller (Retired), Food & Drugs Administration, Haryana; Professor and Head legal, BS Anangpuria Institute of Technology, **Ms. Viveka Roy Chowdhury**, Editor of Express Healthcare and Express Pharma at The Indian Express, **Dr Ruby Sahney**, Joint Medical Superintendent (Sri Ganga Ram Hospital), and expert view by **Mr Ram Khandelwal**, Founder, Heart Health India Foundation. Their insights helped illuminate global and national perspectives on medical device reuse, patient rights, and regulatory pathways.

We acknowledge the guidance provided by the Patient Safety Secretariat, Directorate General of Health Services, Ministry of Health, GoI and insights by its personnel in improving the quality of the paper.

This white paper is not only a policy analysis but also a collective vision for a healthcare system that upholds safety, transparency, and dignity for all.

We hope this document serves as a catalyst for policy dialogue and tangible action, and that it contributes meaningfully to India's ongoing efforts toward building a more equitable and safe healthcare environment.

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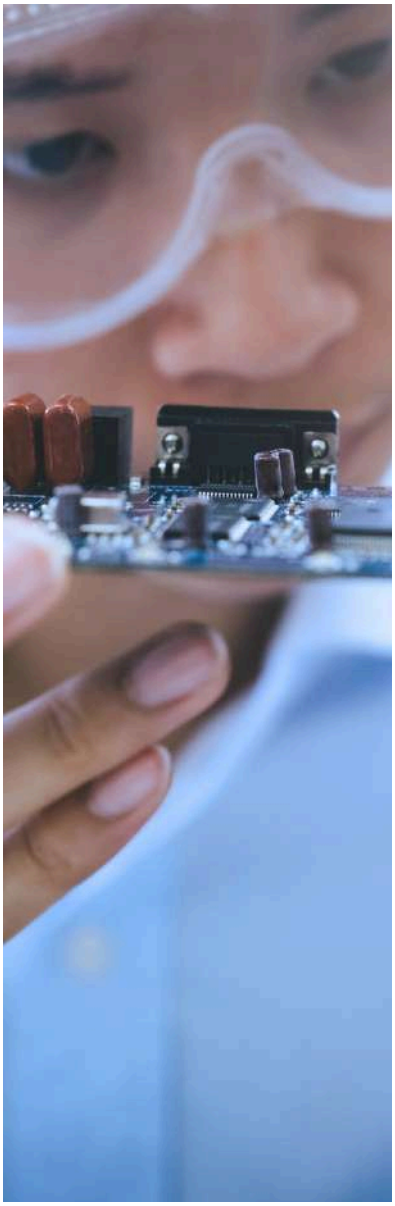
EXECUTIVE SUMMARY

The reuse of **high-end single-use medical devices** (SUDs) has become a prevalent practice in India due to various reasons including economic constraints, resource limitations, and environmental concerns. While reuse offers potential cost-saving benefits, it raises significant risks related to patient safety, ethical standards, and regulatory compliance. While Indian regulations do not define SUDs, the regulators mention that devices labelled as single use must be used according to their labels. But there is a lack of enforcement, and thus there is a need for a comprehensive national guideline for regulating the reuse of high-end high-risk SUDs in India.

The core problem lies in balancing cost-efficiency with patient safety. Reuse of SUDs without robust protocols increases risks of infection, device failure, and ethical concerns, such as the absence of informed patient consent. Furthermore, disparities in care standards disproportionately affect lower-income populations, highlighting systemic inequities. Inadequate regulatory compliance, including inconsistencies in reprocessing methods (such as sterilization), monitoring systems, and stakeholders' engagement, undermines safety and erodes trust in healthcare systems.

This white paper utilized a multifaceted methodology, including desk reviews, Right to Information (RTI) applications, expert webinars, patient testimonials, and diverse stakeholder engagements to identify the problem and potential solution. RTI responses highlighted the absence of national guidelines for SUDs reuse as well as capturing of relevant data points, while expert webinars identified feasible pathways for creating actionable frameworks. Patient testimonials underscored the lack of transparency in device reuse and the critical need for informed consent. Although stakeholder engagement efforts faced limited participation, they emphasized the need for collaborative policymaking.

With the assessment of the above efforts, the white paper recommends for a phased approach to tackle the problem of reuse of high-end SUDs in the Indian context by establishing a national regulatory framework to govern SUDs reuse, and incorporating stringent reprocessing protocols, validation methods, and device-specific reuse limits. Mandating patient awareness campaigns and obtaining explicit informed consent are essential for ethical compliance. Collaborative policymaking involving healthcare providers, patients, and regulatory authorities is critical for developing and implementing guidelines.



INTRODUCTION

The Indian medical devices market is currently valued at approximately $12 billion in 2023 and is projected to grow nearly threefold to reach $50 billion by 2030, with a CAGR of 15%. The Indian medical device market is segmented into five key areas: electronic equipment (56% share), disposables & consumables (26.5%), in-vitro diagnostics (8.1%), implants (7.1%), and surgical instruments (2.3%) [1].

This report focuses only on high-end non-implantable critical consumables and devices, such as electrophysiology diagnostic and therapeutic catheters, sheaths, wires, balloons etc., which come in direct contact with a patient's blood or sterile tissues and are designed as "single-use medical devices" (SUDs).

Indian regulations do not specifically define SUDs. However, the Central Drugs Standard Control Organization (CDCSCO) under the Drugs and Cosmetics Act and the Medical Devices Rules (MDR), 2017, mandates that devices labelled as single use must be used according to their labels. Similarly, the United States Food and Drug Administration (US FDA) defines a SUDs, as one “intended for use on a single patient during a single procedure and not intended to be reprocessed (cleaned, disinfected, or sterilized) for use on another patient”. Both organisations have devised a system to classify medical devices based on their risk of transmitting infection and the areas of the body they will come in contact with [2,3]. The same is captured in the Table below.

Table 1: Classification system for Medical Devices in India and the USA

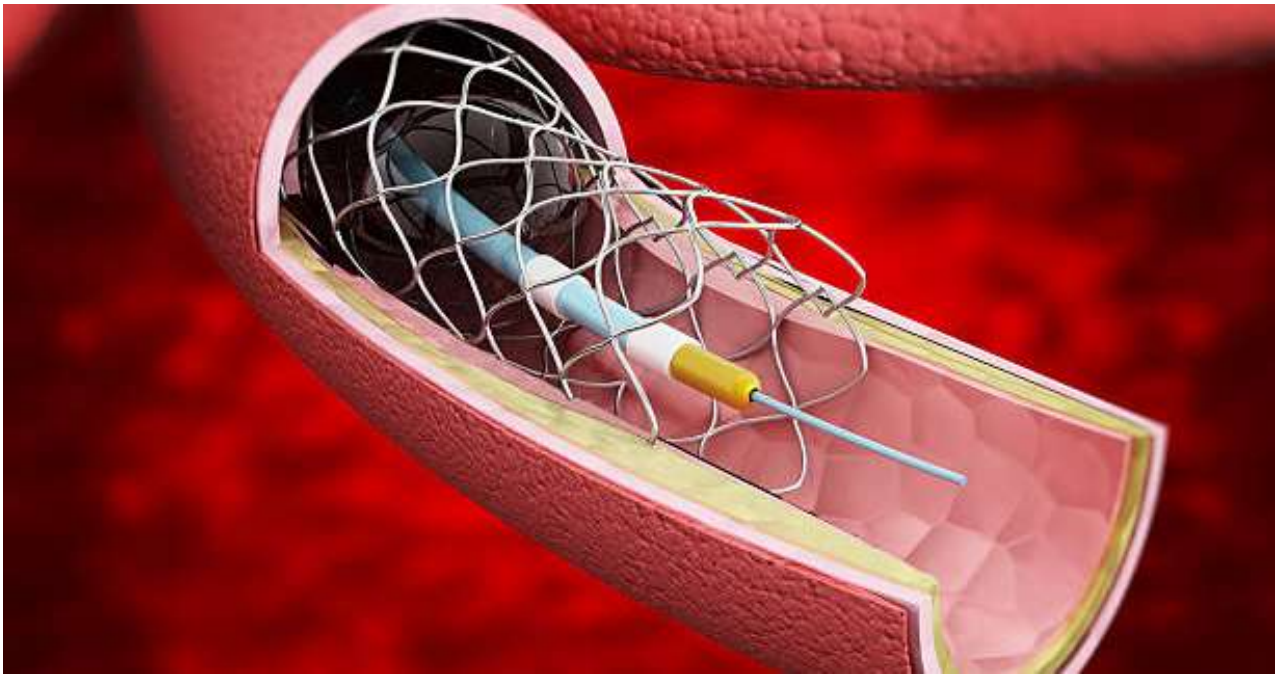
INDIA	USA
The Central Drugs Standard Control Organization (CDCSCO) classifies devices into four risk-based categories: • Class A (low risk), • Class B (low to moderate risk), • Class C (moderate to high risk), and • Class D (high risk). Manufacturers of class C and D devices must register with the Drug Controller General of India and conduct rigorous testing to secure approval.	The US Food and Drug Administration (US FDA) has established a three-class licensing system for medical devices. • Class I, or 'no-critical,' posing minimal risk; most are exempt from regulation but must be registered with the US FDA. • Class II, or 'semi-critical,' devices, carry some unknown risk. Manufacturers must demonstrate risk equivalence to an existing device for approval. • Class III, or 'critical,' devices, including high-risk interventional devices, require Pre-Market Approval with clinical evidence of safety and effectiveness.

However, International agencies such as the USFDA and Association of Medical Device Reprocessors (AMDR) [4] have identified several medical devices that are reused after appropriate reprocessing as laid down in the table below:

Table 2: List of reprocessed devices

SR NO.	SPECIALITY	EXAMPLES
1	Cardiovascular	Percutaneous Ablation Electrode; Guide Wires; Electrophysiology (EP) diagnostic & ablation catheters; EP cables; mapping catheters; coronary sinus catheters etc.
2	Arthroscopic	Arthroscopic shavers; Arthroscopic wands; Bits, burs, and blades; Shavers
3	General Surgery	Infusion pressure bags; Reamers; Suture passers; Soft tissue ablators; Catheter needles
4	Gastro/ Urology	Sealers and dividers; Ultrasonic scalpels; Trocars; Urological catheters; Single needle dialysis set

As a result, the global perception of SUDs influences physician practices and policies regarding their reuse. This makes it imperative for us to assess some global case studies which regulates reuse of high-end non-implantable critical SUDs.



The global market for reprocessed SUDs is projected to grow from USD 3.04 billion in 2024 to USD 8.18 billion by 2031, with a compound annual growth rate (CAGR) of 15% [5]. Globally, the debate around SUD reuse reflects contrasting approaches. Different healthcare systems strive to balance patient safety, environmental sustainability, and economic viability. Reusing and reprocessing SUDs have become essential strategies for hospitals to deliver necessary care around the world. In this section, we will assess some global case studies which regulate the reuse of SUDs.

GLOBAL FRAMEWORK ON REUSE OF SUDs

Table 3: Reuse Practices in major markets

Country	Key Regulations and Guidelines	Best Practices for Reuse	Unique Features
Japan	Structured system for R-SUDs under the PMD Act. Licensing required for remanufacturers. Devices must undergo separate approval. Rigorous QMS and traceability are mandatory [6]	Equivalence in performance and safety, comprehensive training, robust traceability, infection prevention, stakeholder engagement, and promoting awareness.	Annual and five-year inspections by PMDA. Clear framework established since 2017 under the PMD Act.
Australia	Policies by NCCTG and TGA focus on reducing public health risks. Compliance with AS/NZS 4187:2003 for cleaning and sterilizing reusable devices is required. Incident reporting under IRIS is robust [7]	Enhanced cleaning processes, collaboration between healthcare staff, robust incident investigation, standardized reprocessing protocols, and purchasing user-friendly instruments.	Focus on mechanical cleaning methods and collaboration between CSSD staff, infection control teams, and engineers.
United Kingdom (UK)	MHRA advises against reprocessing SUDs unless remanufactured by certified companies. Strict legal and technical standards for reuse must be met [8]	Certified remanufacturing, risk assessment, robust training, adherence to legal frameworks, and focus on patient safety in device selection and reuse.	Legal responsibilities for reuse outlined under UK MDR 2002, with a focus on prion disease prevention and avoiding unsafe reuse.
United States (USA)	FDA regulates reuse of SUDs with stringent protocols. Hospitals and reprocessors classified as 'manufacturers' must meet 510(k) or PMA requirements [9]	Adherence to FDA guidance, stakeholder collaboration, design improvements for easier cleaning, robust risk mitigation, and ongoing training and education.	Risk-based classification for devices (Class I, II, III), with specific timelines for compliance. Comprehensive validation of reprocessing methods.

Box 1: Case Study: Reuse of SUDs in the United States

The FDA regulates the reprocessing of SUDs and has approved 70 such devices for reprocessing. The Medical Device User Fee and Modernization Act of 2002 mandates that all reprocessed SUDs in the US must be labelled as reprocessed and identify the reprocessor. Validation data must be submitted for many reprocessed SUDs. Under this Act, the reprocessed device is considered the product of the reprocessor, not the original manufacturer, and the reprocessor assumes liability.

In the US, device manufacturers provide Instructions for Use (IFUs) to ensure licensed practitioners use the devices safely and as intended. These IFUs must comply with FDA requirements. Users must carefully review the IFUs of reprocessed SUDs and compare them with those from the original manufacturers. Users may not be aware that reprocessors can modify IFUs or that usage limits may differ from those of the original SUDs [10].

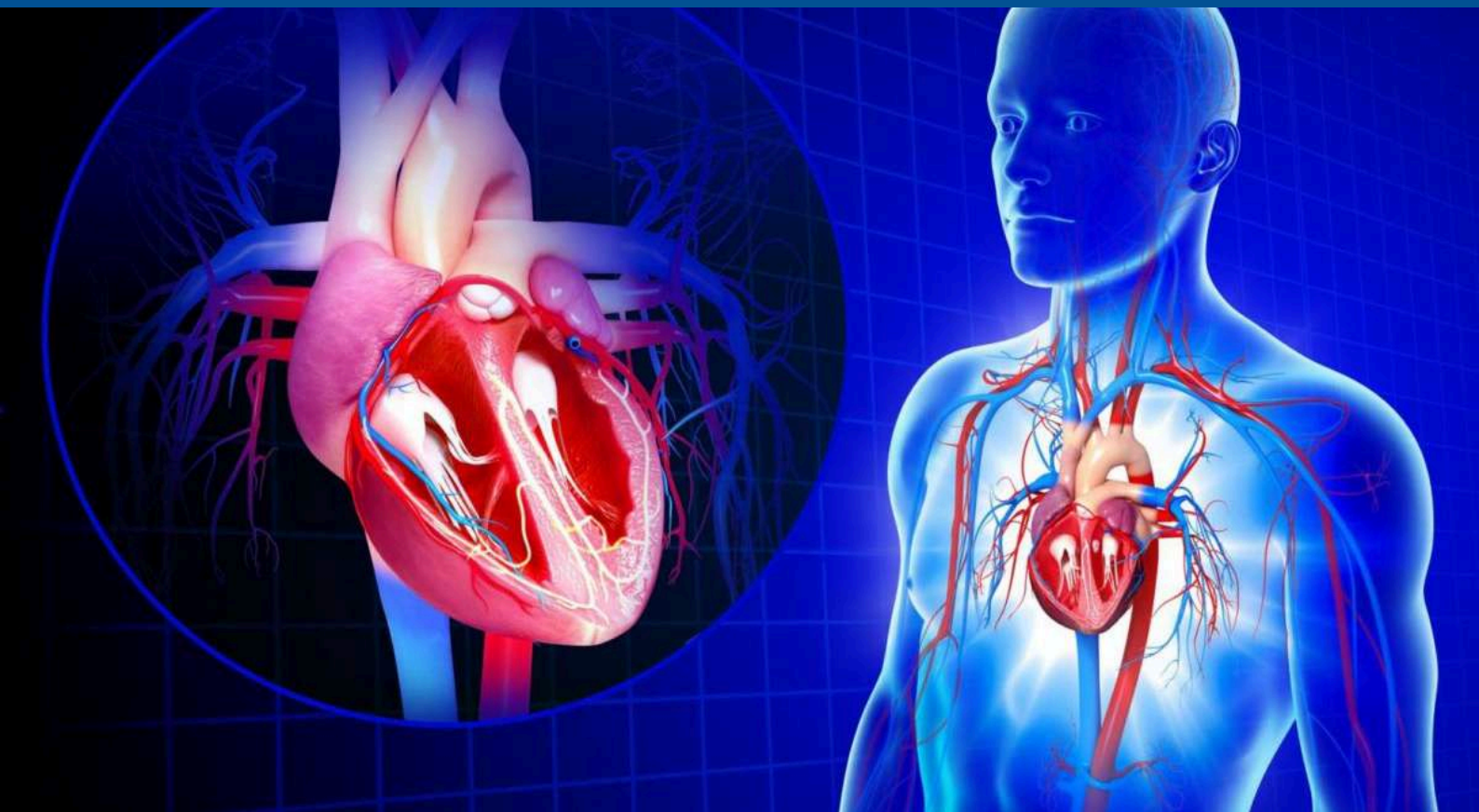
AN ASSESSMENT OF REUSE OF SUDs IN INDIA

While developed nations like the United States regulate reuse of Class II and Class III through stringent oversight and third-party reprocessors, India lacks a cohesive regulatory framework. This ambiguity is compounded by a significant paucity of data, creating a grey area concerning their economic benefits and potential harms. The voluntary nature of adverse event reporting further exacerbates this issue, as it may not capture the necessary data comprehensively.

However, to understand the existing policies and practices related to the reuse of SUDs across India, we filed RTIs (Right to Information) with various government departments, institutions and hospitals. The objective was to gather information on whether any standard operating procedures (SOPs), reprocessing protocols, or guidelines exist for the safe reuse of SUDs. Additionally, queries were raised regarding documentation of safety, efficacy, patient consent, quality control measures, and any regulatory frameworks governing the reuse of such devices.

In August 2024, four RTI applications were filed with the Department of Pharmaceuticals (DoP), the Ministry of Health (DGHS), the Department of Health Research (DHR), and the Indian Council of Medical Research (ICMR). To gather additional information, five more RTI applications were submitted in September 2024 to AIIMS Delhi, Safdarjung Hospital, the Central Government Health Scheme (CGHS Delhi), the National Health Authority (NHA – PMJAY), and the Insurance Regulatory and Development Authority of India (IRDAI). A further RTI related to procurement was filed with AIIMS Delhi in October 2024 as well.

The RTI responses received from most departments and hospitals indicated the absence of relevant guidelines/ policies, SOPs, or ethical standards regarding the reuse of SUDs.



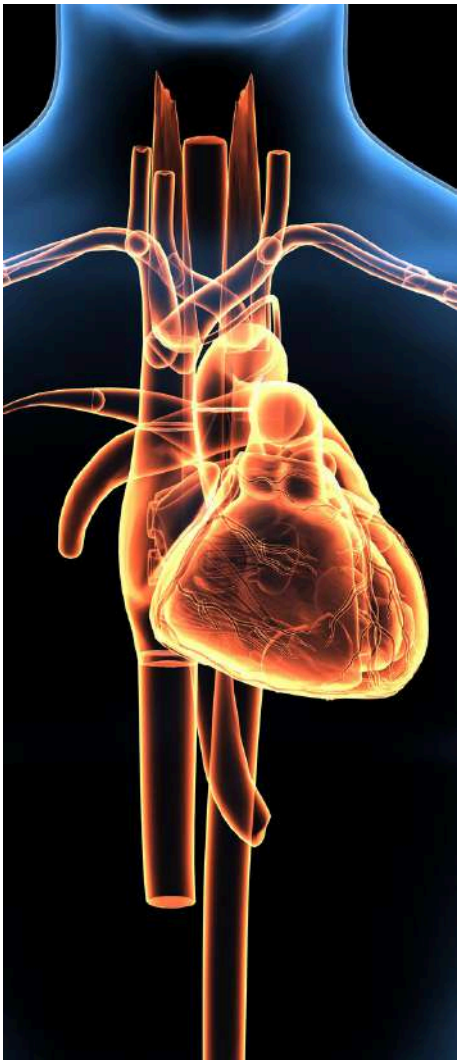
COMPLEXITIES OF REUSE OF HIGH-END NON-IMPLANTABLE CRITICAL SUDs

The Biomedical Waste Management and Handling Rules of 1998 focus on waste disposal rather than device reprocessing, leading to varied practices across healthcare sectors. Inconsistent reprocessing methods, such as ethylene oxide sterilization and gamma irradiation, and minimal emphasis on validating the functional integrity of reused devices raise significant patient safety concerns [11,12].
Therefore, there is a need to critically understand the challenges associated with inconsistent reprocessing and sterilization practices in India:

- **Infrastructure Deficiencies:** Many hospitals lack industrial-grade reprocessing units, relying on basic in-house facilities that often fail to meet stringent requirements.
- **Operational Costs:** High costs associated with advanced reprocessing and sterilization methods like ethylene oxide or hydrogen peroxide plasma limit their use, affecting the sterilization quality.
- **Lack of Standardization:** Without formalized industry standards, there is no consistent approach to pricing, quality control, or safety protocols for reused devices, leading to potential harm to patients.
- **Unreported adverse events:** The absence of uniform guidelines and outcome tracking for reused products may result in unreported adverse events, compromising healthcare standards.

Additionally, it is also pertinent to consider other critical aspects around the reprocessing of SUDs, few of them are laid out below:

- **Material Degradation:** Repeated sterilization can weaken, warp, or rust SUDs, compromising their integrity and functionality, increasing the risk of errors and reducing device lifespan [13].
- **Device Failure:** Reused devices may not perform effectively, leading to malfunctions during procedures, resulting in life-threatening complications. Catheters like electrophysiology ablation catheters has lumen for irrigation, and there is a chance that lumen can get blocked with clot and therefore pose serious procedural complications.
- **Infection Risks:** Inadequate reprocessing can leave behind pathogens, increasing the risk of cross-contamination and healthcare-associated infections (HAIs) [11,14]. Biofilm formation on catheters can lead to persistent infections, while prions pose significant contamination risks [15,16].
- **Legal Risks:** Non-compliance with regulations on SUDs can lead to legal penalties and loss of accreditation for healthcare facilities. Additionally, harm caused by reused devices can result in lawsuits and damage to the institution's reputation.
- **Ethical Risks:** Reusing SUDs without patient consent breaches trust and is considered unethical. It raises concerns about inequality in care, as patients in low-resource settings are more likely to receive reused devices. Balancing patient safety with cost savings poses significant ethical dilemmas.



FACTORS FOR REUSE OF SINGLE USE MEDICAL DEVICES

Despite the inherent risks, reprocessing of high-end non-implantable SUDs remains prevalent, particularly in resource-constrained settings like India, where the healthcare providers are largely focused on cost optimization of medical equipment and devices. Hence, it becomes important to assess, as to why reuse is so much prevalent in India. The current section outlines the factors promoting the reuse of SUDs in India:

ECONOMIC FACTORS

- Medical devices represent a significant portion of healthcare expenses in India. With rising healthcare costs, hospitals are reusing medical devices sterilized in-house without any regulatory guidelines in India.
- Unlike new medical devices, the prices of reused SUDs are largely unregulated in India. Alarmingly, many hospitals fail to obtain informed consent from patients and sometimes engage in profiteering by charging for new devices while using reused ones [17,18].
- The growing adoption of health insurance in India has influenced the pricing of medical devices. Insurance companies often reimburse hospitals based on fixed rates for procedures, and these reimbursements may not fully cover the actual costs of high-end devices, which encourages hospitals to charge for the same device multiple times.
- In certain healthcare settings, especially in low-resource areas or during shortages, there may not be enough supply of SUDs, prompting reuse to ensure continued patient care.

Box 2: Economic Implications of Reuse of SUDs

A Maharashtra FDA report found that some private hospitals were charging patients 77% of the MRP for reused catheters, with used balloon catheters priced at ₹20,000 against an original MRP of ₹26,000. The absence of a specific price cap for reused devices results in unregulated pricing policies. According to the Hindustan Times, charging near-MRP prices for SUDs may be unethical, but there are no legal provisions from the Medical Council of India, health ministry, or FDA to prevent it. Following the FDA investigation, police filed a report on reused device pricing. Without a market for reprocessing and clear regulations, the situation for reusable devices in India remains unorganized [19].

ENVIRONMENTAL CONCERNS

The growing awareness of medical waste and environmental sustainability has led some healthcare organizations to explore reusing devices to minimize waste and reduce the environmental impact of disposable products.

PERCEPTION OF DURABILITY

Many SUDs are designed with high-quality materials and may appear durable enough to be reused, leading healthcare workers to believe that they can safely be reprocessed despite the original labelling.

WEAK ENFORCEMENT OF REGULATIONS

In India, despite improvements in medical device regulation, critical gaps remain in the rules surrounding reprocessing, which may compromise patient safety, ethical standards, and healthcare quality.

- **Lack of Enforcement and Comprehensive Regulatory Framework:** The Medical Device Rules (2017) do not cover the reuse or reprocessing of SUDs, creating a regulatory void. This lack of clarity on roles and responsibilities can lead to unsafe practices, as healthcare providers may inadvertently compromise patient safety and ethical standards without clear directives.
- **Absence of Comprehensive National Guidelines:** There is no unified framework to define which SUDs can be safely reprocessed. This lack of a standardized approach leads to inconsistent practices across healthcare facilities.
- **Inadequate Monitoring and Enforcement:** The lack of robust inspection and certification systems for reprocessing means there is no effective oversight to ensure it is conducted safely and in compliance with best practices. Furthermore, the absence of stringent penalties for unsafe or non-compliant procedures allows such practices to persist, further endangering patient safety.

LACK OF PATIENT AWARENESS

Many patients in India may not be fully aware of the risks and regulatory concerns surrounding reused medical devices.

RECOMMENDATIONS

In countries like India, the reuse of SUDs is common despite its risks. To address this, we need a phased approach to formalize and regulate this practice for the identified high-end non-implantable critical SUDs. This white paper outlines key recommendations for a standardized pathway forward:

SHORT TERM

1. Advisory to Hospital for Compliance: The Government to issue an advisory to all hospitals, both public and private, strictly adhere to the Medical Device Regulation (MDR) Rules for SUDs. Hospitals must use SUDs according to their labels, prohibit unauthorized reprocessing, and establish compliance protocols.

MID TERM

1. Promote Public Awareness: Sensitize patients by driving awareness campaigns and encourage balanced media reporting to inform patients about their rights and the guidelines in place.Inform patients about their rights, the guidelines in place, the concept of reuse of SUDs, its outcomes, and the economic benefits hospitals should pass on to them.

2. Informed Patient Consent: To ensure transparency, should be informed about the type of medical device being used or reused, the benefits and risks, and the option to choose a new device at an additional cost. Consent forms should clearly outline these details. Reuse charges should be limited to reprocessing costs plus a nominal fee, to be capped appropriately of the device's original price. A draft Patient Consent form is included in the Appendix II.

3. Formation of an expert group: comprising of healthcare providers, regulatory bodies, and patient advocates to propose comprehensive guidelines on regulated and limited reuse.

LONG TERM

1. Development of Guidelines on Limited reuse of SUDs in India: The expert group to work towards formulation of comprehensive guidelines on regulated and limited reuse.

Suggested List of Indicators to be considered for Reprocessing of SUDs
• Type of SUDs allowed for reuse • Tracking of each reuse • Associated Quality Systems • Standard Operating Procedures • Training • Risk parameter for reuse of such devices in patients • Reprocessing protocols • Labelling of reprocessed device • Number of times SUDs can be reused • Validation of the effectiveness of reprocessing

APPENDIX I: METHODOLOGY

To understand the policies related to the reuse of SUDs in India, a comprehensive desk review was conducted. The review aimed to gather information on the existing regulatory frameworks and guidelines governing the reuse of SUDs in the country. The study was initiated in August 2024 and is ongoing.

The methodology involved multiple approaches to ensure a thorough exploration of the subject:

1. Right to Information (RTI) Applications: RTI requests were filed with various government departments to obtain official information on policies and practices concerning the reuse of SUDs.
2. Expert Webinars: Webinars were organized to engage with subject-matter experts, including policymakers, medical professionals, and legal advisors. These sessions provided insights into current practices and regulatory challenges.
3. Patient Testimonials: Testimonials were collected from patients who had undergone medical procedures involving the use of SUDs. These testimonials offered firsthand perspectives on the implications of SUD reuse.
4. Stakeholder Engagement: Open-ended questionnaires were designed to gather qualitative data from key stakeholders involved in policymaking, including healthcare providers, industry representatives, and regulatory authorities. The questions aimed to elicit comprehensive views on the feasibility, safety, and ethical considerations of reusing SUDs.

SEEKING INFORMATION THROUGH RTIs

To understand the existing policies and practices related to the reuse of SUDs in hospitals across India, multiple RTI (Right to Information) applications were filed with various government departments and institutions as mentioned previously. The objective was to gather information on whether any standard operating procedures (SOPs), reprocessing protocols, or guidelines exist for the safe reuse of these devices. Additionally, queries were raised regarding documentation of safety, efficacy, patient consent, quality control measures, and any regulatory frameworks governing the reuse of such devices. The responses revealed significant gaps in policies, with most departments indicating that no such guidelines or standardized procedures are currently available or followed.

TWO EXPERT WEBINARS

The first webinar titled "**Reuse of Designated Single Use Medical Device: An Expert's Viewpoint**" focused on understanding the existing landscape regarding the reuse of SUDs in India. Experts discussed the absence of standardized guidelines and regulatory frameworks governing SUD reuse in the country. The second webinar titled "**Pathways to Solutions: Developing Guidelines for SUD Reuse**" aimed to explore actionable solutions and best practices to address the challenges identified in the first session. It focused on identifying feasible pathways to ensure the safe and effective reuse of SUDs in India while reducing healthcare costs. The topics outlined below represent a consolidated account of the discussions held during the two webinars (Quotes from Speaker in box):

OVERVIEW OF SUD REUSE PRACTICES:

- A detailed discussion on the global and national practices of SUD reuse.
- Examination of safety, efficacy, and ethical concerns associated with reprocessing SUDs.
- The burden of Reuse in India
- The existing reprocessors authorised by regulatory agencies in many countries follow stringent guidelines, tracking and highest standards of safety and efficacy.

BOX 3: Quotes from speakers highlighting "overview of SUD reuse practices"

"The term 'single-use' is not always scientifically defined—it's often a commercial label, not a regulatory one."

— Dr. Amit Vora, Consultant Cardiologist and Cardiac Electrophysiologist

"Reprocessed medical devices in the U.S. go through more rigorous scrutiny than even some original devices."

— David Sheon, Vice President, Strategic Initiatives and External Affairs, AMDR

"While diagnostic safety is our focus for World Patient Safety Day 2024, the conversation around medical device reuse remains a critical yet under-discussed area of patient safety in public health."

— Dr. Ratna Devi, CEO, DakshamA Health

REGULATORY GAPS

- Emphasis on the lack of specific Indian regulations addressing SUD reuse, unlike developed nations such as the USA, which have stringent guidelines for reprocessing.
- Challenges posed by unregulated in-house reprocessing in Indian hospitals.
- Deliberation on balancing the economic benefits of reprocessing SUDs with the imperative of maintaining patient safety.
- Recommendations for establishing standardized protocols for cleaning, sterilization, and validation of reprocessed devices.

BOX 4: Quotes from speakers highlighting "regulatory gaps"

"The current legal framework lacks provisions for the reuse or reprocessing of SUDs, leaving hospitals vulnerable to legal and ethical challenges."

— Adv. Narender Ahooja, Professor and Head legal BS Anangpuria Institute of Technology

"In many parts of the world, the same device is labeled 'single-use' in one country and reusable in another—it's a regulatory grey zone driven by manufacturers."

— David Sheon, Vice President, Strategic Initiatives and External Affairs, AMDR

PATIENT AWARENESS AND CONSENT

- Highlighted the importance of educating patients about the reuse of SUDs and ensuring explicit informed consent.
- Ethical concerns were raised about patients often being unaware of the reuse of such devices.
- Strategies for engaging patients, caregivers, and healthcare providers to promote transparency and ethical practices.

Box 5: Quotes from speakers highlighting "patient awareness and consent"

"Patients deserve to know if a reused device is being used—it's their body, their treatment, and their right."

— Dr. Amit Vora, Consultant Cardiologist and Cardiac Electrophysiologist

"Informed consent is not a checkbox—it's a conversation rooted in respect and transparency."

— Sairekha Suresh, Founder, T1D Foundation

"It's imperative to replace verbal patient consent with written agreements to enhance transparency and legal protection."

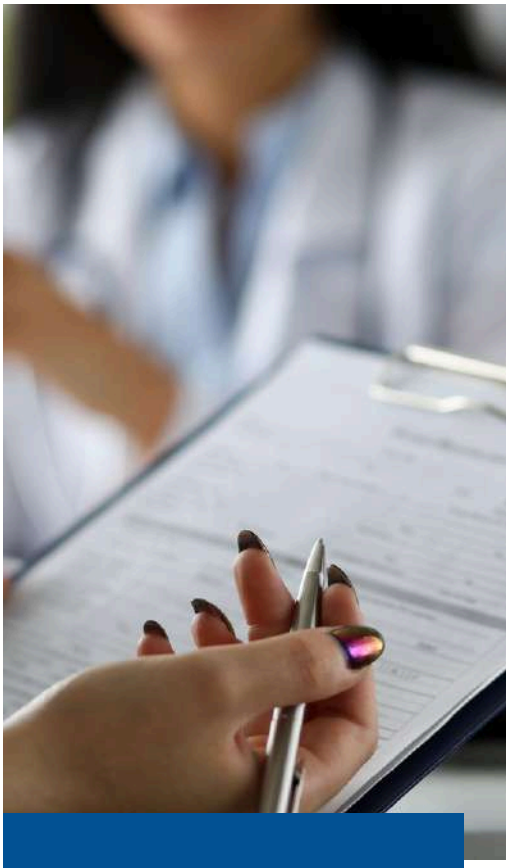
— Dr. Ruby, Deputy Medical Superintendent, Sir Ganga Ram Hospital; NABH Assessor

STAKEHOLDER PERSPECTIVES

- Insights from healthcare providers, patients, and regulatory experts underscored the need for a robust regulatory framework to ensure safety and quality standards.
- Cardiologists, Policymakers, and Payers emphasized the importance of collaborative policymaking.
- The current acts do not have the legislative provision for including reuse as a mandatory procedure and will need realignment. The revised Drugs and Cosmetics Act which is pending legislative approval will be able to address this lacuna.

Patient testimonials highlight the critical need for transparency and informed consent regarding the reuse of SUDs. A partnership was sought with Heart Health Foundation India- a patient advocacy organisation working on heart health. Discussions were held with the founders to understand key selection criteria for the testimonials. Most patients were unaware of whether the devices used in their treatments were new or reused, as this information was not explicitly disclosed to them. While they appreciated the professional care received and reported positive treatment outcomes, they emphasized that being informed about the devices used is essential for trust and ethical medical practices. Many believed that having the choice or at least being informed about reused devices would have provided peace of mind, particularly given the potential risks associated with hygiene and safety.

Patients acknowledged the cost-saving advantages of reusing medical devices but stressed that safety and efficacy must always take precedence. They called for stringent guidelines and protocols to ensure the safety of reused devices, especially in the post-COVID era where the risk of infections is heightened. Ultimately, the need for transparency, robust regulatory practices, and clear communication between healthcare providers and patients was identified as crucial to fostering trust and ensuring quality.



PATIENT TESTIMONIALS

STAKEHOLDER ENGAGEMENT

77 stakeholders were identified and approached to gather in-depth insights on the reuse of SUDs in India. These stakeholders included representatives from the healthcare industry, officials from the Ministry of Health and Family Welfare, the Indian Council of Medical Research (ICMR), professional medical associations, patient organizations, and healthcare providers. An open-ended questionnaire was designed to facilitate in-depth interviews, focusing on the awareness, practices, and policies surrounding the reuse of SUDs. The outreach began with an email campaign on September 18, 2024, followed by structured follow-ups on October 1, 2024, and November 5, 2024, to reinforce the request for engagement. Despite the comprehensive approach and persistent efforts, no responses were received from the contacted stakeholders.

To encourage participation, reminder emails were sent, and stakeholders were approached via phone calls and WhatsApp messages. Efforts were also made to arrange in-person meetings to secure their input. The engagement strategy targeted 4 industry representatives, 15 ministry officials, 25 members of professional associations, and 11 patient organization representatives.

APPENDIX II: PATIENT INFORMED CONSENT FORM

Hospital Details

Name of the Hospital: _____

Department: _____

Sub-department: _____

Patient Details

Patient ID: ____

Name of the patient: _____ Age/Sex: _____

Address: _____

Tel. No(s).: _____

Treatment Details

Differential Diagnosis: _____

Treatment/Procedure: _____

Date of Admission: _____ Date of Procedure: _____

Name of the Principal Physician: _____

Introduction: You are scheduled to undergo a medical procedure that may involve the reuse of SUDs. This form is intended to provide you with information about the reuse of these devices, the associated risks, and to obtain your informed consent.

Description of Reuse: SUDs are typically designed for one-time use. However, due to various factors, including cost and resource constraints, these devices may be reprocessed and reused. Reprocessing involves cleaning, disinfecting, and sterilizing the device to ensure it is safe for reuse.

Potential Risks: While reprocessed devices are subjected to rigorous cleaning and reprocessing processes, there are potential risks associated with their reuse, including:

- Infection
- Device malfunction
- Allergic reactions
- Pyrogen reactions
- Severe infections such as infective endocarditis

Benefits: Reusing SUDs can help reduce healthcare costs and make medical procedures more accessible. It also contributes to environmental sustainability by reducing medical waste.

Alternatives: You have the option to request the use of a new, SUD for your procedure. Please discuss this with your treating physician to understand the implications and any additional costs involved.

Consent Acknowledgment: I have read and understood the information provided above regarding the reuse of SUDs. I have had the opportunity to ask questions and have received satisfactory answers. I understand the potential risks and benefits and consent to the reuse of SUDs for my procedure.

Patient **Signature:** _____

Date: _____

Physician **Signature:** _____

Date: _____

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ABOUT THE ORGANISATION

Dakshayani and Amaravati Health and Education (DakshamA Health) is a Section 8 not for profit organisation working with various stakeholders to improve health outcomes . Since its inception in 2012, the organization has been dedicated to strengthening the health ecosystem through impactful initiatives focused on capacity building, awareness generation, and health education—not only for service providers but also for patients and caregivers.

With a strong emphasis on chronic non-communicable diseases, rare conditions, and patient safety, DakshamA Health has successfully led numerous projects that bridge the gap between healthcare delivery and community needs. The organization's work is rooted in the belief that education, early intervention, and collaborative action are essential to achieving a healthier society.

DakshamA Health is deeply committed to empowering communities by promoting an accessible and efficient healthcare system that prioritizes the safety, quality, and dignity of care. Its approach integrates prevention, advocacy, and education, leveraging technology and innovation to reach diverse populations across India.