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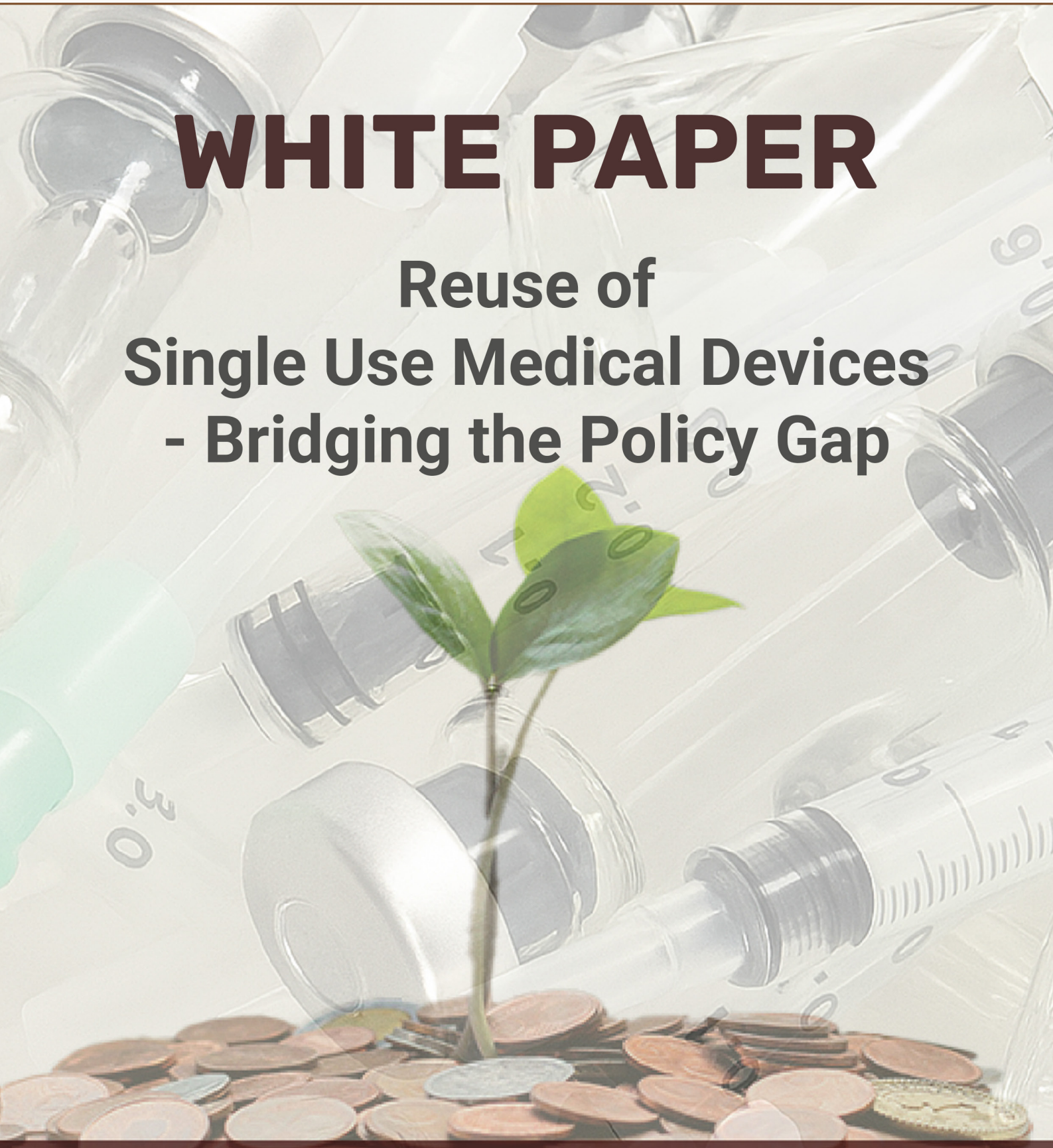
WHITE PAPER

Reuse of Single Use Medical Devices - Bridging the Policy Gap



10th National Convention on Medicine & Law 2025

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White Paper on

Reuse of Single-Use Medical Devices – Bridging the Policy Gap

THIS WHITE PAPER documents the deliberations and recommendations of the 10th National Convention on Medicine & Law 2025, organized by the Institute of Medicine & Law on 23rd November 2025. This document is intended for Indian policymakers, regulators, statutory authorities, and Members of Parliament. It identifies and discusses the legal, social, and systemic issues arising from the lack of policy and regulations governing the reuse of single-use medical devices and proposes practical, legally appropriate, and India-specific solutions.

Reuse of Single Use Medical Devices - Bridging the Policy Gap

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1.1. The Core Dilemma

The Indian healthcare ecosystem stands at a critical juncture where the dual imperatives of expanding clinical access and maintaining uncompromised patient safety frequently collide. This systemic friction is most acutely manifested in the unregulated, pervasive practice of reusing single-use medical devices (SUDs). Ostensibly labelled by original equipment manufacturers (OEMs) for a single application in a single patient during a lone procedure, high-cost medical devices, ranging from cardiac catheters and angioplasty balloons to laparoscopic shears and haemodialysis filters are routinely reprocessed and reused across both public and private healthcare facilities in India.

The 10th National Convention on Medicine & Law 2025, organized by the Institute of Medicine & Law, served as a collaborative, non-adversarial forum to dissect this complex phenomenon. The Convention brought into sharp focus an inescapable ground reality: the reuse of SUDs is a systemic necessity driven by economic compulsions, yet it operates within a profound regulatory vacuum. This lack of legal recognition fosters a precarious "conspiracy of silence" involving doctors, hospitals, and even manufacturers. The term "single use" is designated by manufacturers based on their risk assessments, often without scientific validation and sometimes with a profit motive.

1.2. The Policy Gap

The primary policy gap lies in the total absence of a statutory framework governing the reprocessing, testing, validation, and clinical deployment of reprocessed SUDs within the Indian regulatory architecture. Currently, the Central Drugs Standard Control Organisation (CDSCO), operating under the Drugs and Cosmetics Act and the Medical Devices Rules, maintains an ambivalent posture. While manufacturing standards for new devices are tightly codified, the law remains silent on the legal status

of an entity, whether a hospital or a third-party processor, that alters the clinical lifecycle of a device through reprocessing.

This regulatory blindness forces individual institutions to formulate fragmented, ad-hoc internal guidelines. Without national benchmarks for microbial decontamination, functional testing, pyrogen clearance, and structural integrity, the safety profile of reprocessed devices varies dangerously from one facility to another. Paradoxically, while statutory authorities ignore or penalize the private reuse of SUDs during clinical establishment audits, State and Central government procurement agencies explicitly incentivize reuse in public-private partnership (PPP) tenders for services such as haemodialysis to lower fiscal bids. This underscores the urgency of a unified national policy.

1.3. The Systemic Impact & The Urgency

The failure to address this policy gap carries severe, far-reaching consequences for all primary stakeholders in the healthcare delivery chain:

- **For Patients**

  The status quo exposes patients to an asymmetric information matrix. Reuse is often concealed, denying patients their fundamental right to be informed. Furthermore, the patient may be billed the maximum retail price (MRP) for a new device while unknowingly receiving a reprocessed device. Conversely, in the absence of a legal reuse pathway, impoverished patients are unable to access lifesaving, expensive treatment.

- **For Healthcare Providers**

  Doctors operate under immense legal vulnerability. If a reprocessed device fails mechanically or causes a healthcare-associated infection (HAI), the burden of proof in court shifts to the operating surgeon and the hospital. In a climate where violence against healthcare workers is escalating, a single adverse event linked to an unacknowledged

reprocessed device can irreversibly damage a doctor's professional reputation and trigger legal proceedings.

- **For the Healthcare System**

  The financial and environmental sustainability of Indian healthcare gets severely affected. Adhering strictly to the "one-and-done" model favoured by device manufacturers would generate an unsustainable mountain of high-density plastic biomedical waste, expanding the nation’s carbon footprint. It would also exhaust insurance pools and state exchequers under schemes like Ayushman Bharat (PM-JAY), where institutional reimbursement ceilings are often lower than the baseline cost of new imported devices.

2. The Ground Reality – Perspectives from the Stakeholders

The deliberations at the Convention revealed a deeply fragmented landscape of competing priorities, technical rationales, and legal interpretations among the key actors in the ecosystem. Synthesizing these viewpoints underscores the urgent need for a cohesive regulatory framework.

2.1. Doctors & Healthcare Professionals

The reuse of medical devices is not a choice but an ethical imperative for doctors to preserve human life. For the vast majority of Indian patients, demanding the use of a new device amounts to denying the procedure altogether, directly endangering lives.

In fields such as emergency medicine, cardiology, and nephrology, the reuse of high-cost devices is an everyday reality driven by patient demographics. 40% to 60% of high-cost procedures, such as those involving PTCA balloons, guide wires, catheters, and endoscopic clips, involve the reuse of devices. A single dialyzer filter costs thousands of rupees. For a patient requiring maintenance haemodialysis three times a week, a strict single-use mandate could be a financial death sentence. Similarly, a new imported cardiac catheter costs approximately Rs. 1.8 to 3.5 Lakh, whereas a properly reprocessed device costs Rs. 40,000 to 80,000.

Doctors argue that clinical outcomes are not inherently compromised by reuse, provided reprocessing protocols are rigorous and scientifically validated. Decades of peer-reviewed data from premier Indian public institutions show that haemodialysis filters can be safely reused 10 to 14 times for the same patient without increasing risk or compromising efficiency. From a clinical perspective, the absolute risk of denying a

procedure due to cost far outweighs the managed, marginal risk of using a rigorously sterilized, functionally verified reprocessed device.

2.2. Legal Experts & Judiciary

The legal fraternity approaches the issue through the lenses of strict liability, consumer protection, and constitutional guarantees.

The current practice relies on a dangerous "conspiracy of silence." Because no statutory law explicitly permits or regulates the reuse of SUDs, any institutional failure that results in patient injury is treated as a prima facie deviation from the standard of care, thereby meeting the legal definition of medical negligence.

Further, the legal consensus is that "good faith" intentions do not constitute a valid defence in a court of law if a doctor knowingly overrides a manufacturer's explicit "single-use" warning in the absence of a validated institutional protocol and an executed informed consent document.

On the other hand, the Supreme Court has repeatedly affirmed that the right to life guaranteed under Article 21 of the Indian Constitution encompasses the right to health, including access to affordable healthcare. Therefore, a regulatory regime that effectively bars cost-saving reuse could be challenged as unconstitutional if it interferes with life-saving care in any way.

2.3. Patient Safety Advocates

Patients do not inherently fear the reuse of medical devices; rather, they fear the deception and lack of safety assurances that accompany hidden reuse. The primary grievance thus is ‘hidden reuse’. Patients expect three basic rights: to know what is being used on them, to have proof that it is scientifically validated as safe, and to not be billed for a new device when a reprocessed one is used. Hospitals engage in illegal

billing, charging for a brand-new device while deploying a reprocessed asset. This is a clear breach of trust and ethics, amounting to cheating.

An immediate transition to absolute transparency is required. Patients must have the autonomy to exercise a "right of refusal." For a financially secure patient who wishes to pay a premium for a virgin device to eliminate any perceived risk, that choice must be legally protected. For a patient who opts for a reprocessed device due to economic constraints, the hospital must provide absolute assurance that the device has undergone validation identical to that of a new one, along with a transparent discount on the final invoice. Trust is the ultimate currency of healthcare delivery, and it can only be preserved through institutional honesty.

2.4. Industry Representatives & Administrators

The MedTech industry has an essential counterargument rooted in materials science, engineering complexity, and quality assurance. Industry bodies strongly reject the notion that the "single-use" designation is a mere commercial gimmick intended to inflate corporate revenues.

Modern tertiary devices are engineered with highly complex micro-lumens, delicate hydrophilic or drug-eluting polymer coatings, epoxy-bonded joints, and thermolabile plastics. These materials are inherently non-reusable. Exposing a catheter with a micro-lumen or a drug coating to repeated cycles of high-temperature steam sterilisation or harsh chemical sterilants such as ethylene oxide or glutaraldehyde alters the plastic's molecular matrix. This can lead to material embrittlement, stress cracking, and intra-procedural fragmentation. Delamination of drug coatings can cause structural failure or toxic systemic release. Pyrogen clearance and complete removal of highly resilient pathogens or residual toxic chemical sterilants cannot be guaranteed.

India currently lacks the mature regulatory infrastructure required for safe reuse, such as Unique Device Identification (UDI) systems and mandatory, robust Materiovigilance Programs (MVPI) for adverse event reporting.

Furthermore, the hospital's Central Sterile Supply Departments (CSSDs) face significant operational challenges. Most Indian hospitals lack the advanced automated testing benches, cleanroom environments, and specialised biomedical engineering expertise required to validate the tensile strength, lumen patency, and electronic integrity of a reprocessed device. Consequently, hospital-level reprocessing remains an unstandardised improvisation, creating significant quality-assurance gaps.

3. Evidence, Data & Precedents

A key strength of any policy reform is its grounding in rigorous empirical evidence and established legal precedents. Localized institutional data and comparative global regulatory analyses will help chart a viable pathway for India.

3.1. Institutional Proof – The Aravind Eye Care Model

Dr. R. D. Ravindran, Chairman of Aravind Eye Care System, presented data challenging the Western "one-and-done" paradigm. Aravind Eye Care, globally recognised for high-volume, low-cost, high-quality ophthalmic surgery, performs hundreds of thousands of cataract surgeries annually (7,34,000 procedures, including 4.5 Lakh cataract surgeries), providing free or heavily subsidised care to over 50% of its patients.

Aravind's operational protocols involve the continuous, structured reuse of surgical gloves, drapes, tubing, and phacoemulsification cassettes across consecutive cases, using rigorous, highly standardized short-cycle steam sterilization and validated chemical disinfection.

To demonstrate the safety of this approach, Aravind conducted a prospective, multi-year study covering more than 1 million consecutive cataract surgeries. The resulting peer-reviewed data, published in journals such as The Lancet and Ophthalmology, showed that the post-operative endophthalmitis (intraocular infection) rate remained consistently at 1 to 2 cases per 10,000 surgeries (0.01% - 0.02%). This is equal to or better than the infection rates reported in the United States and the United Kingdom, where regulatory bodies mandate that, every single component be discarded after a single use.

Furthermore, environmental impact analyses by Fulbright scholars found that while a standard Western cataract surgery (US & UK)

generates 2.5 to 5 kilograms of plastic and hazardous waste, the Aravind model produces only 40 grams of hazardous solid waste. The corresponding Carbon Footprint Equivalence is 500 km of driving versus 25 km of driving. This demonstrates that scientifically validated reuse can simultaneously achieve clinical excellence, environmental sustainability, and radical cost reduction.

3.2. Legal Precedents – The Shadow of Fraud

The landmark Supreme Court judgment in Samira Kohli v. Dr. Prabha Manchanda (2008) primarily set out the parameters of informed consent in Indian medicine. It emphasized that consent must be real, specific, and intelligent. In the context of medical devices, deploying a reprocessed instrument without explicit disclosure invalidates the patient's consent, rendering the procedure an actionable tort of battery and medical negligence, irrespective of the clinical success of the operation.

In an environment lacking clear regulatory oversight of reprocessed devices, predatory institutions can easily exploit the system by buying low-cost devices, reprocessing them illicitly, and billing patients, the State exchequer, or insurance companies for full-price virgin items. This reality underscores that a reuse policy is not merely an economic convenience but a necessary regulatory mechanism to eliminate corporate fraud and protect public funds.

3.3. Global Regulatory Frameworks – A Comparative Analysis

Analysing how foreign jurisdictions have legally integrated the reuse of SUDs will help provide direction and clarity on the road ahead for policy changes.

3.3.1. United States – US FDA Pathway

Under the Medical Device User Fee and Modernization Act (MDUFMA), the US FDA permits the reprocessing and reuse of SUDs while

subjecting them to strict regulatory oversight. Any entity that reprocesses an SUD, whether a specialised third-party commercial re-processor or an in-house hospital biomedical department, is legally classified as a ‘Manufacturer’. They must submit a pre-market notification or seek Pre-Market Approval (PMA), providing scientific validation data demonstrating that the reprocessed device is as safe and effective as a brand-new device. The US system relies on Unique Device Identification (UDI) barcodes to track each device throughout its verified lifecycle, mandating immediate destruction once the pre-validated maximum number of reuses is reached.

3.3.2. Germany – The Unified Standard

The Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM), help in maintaining a unique, non-discriminatory regulatory stance in Germany. The German framework does not distinguish between "single-use" and "reusable" devices based on the manufacturer’s label. Instead, it focuses entirely on cleaning and sterilisation. If an institution complies with the stringent, standardised reprocessing requirements set out in the German Medical Devices Act, it can legally reprocess any device, shifting the burden of safety from corporate labels to objective processing metrics.

3.3.3. United Kingdom – MHRA Position

The Medicines and Healthcare products Regulatory Agency (MHRA) strongly discourages the reuse of SUDs but stops short of an outright statutory ban. The MHRA specifies that if an institution resterilises an SUD contrary to the manufacturer's instructions, the original manufacturer is fully absolved of product liability. The institution assumes full civil and criminal liability for the device's mechanical and microbiological performance, and acts as the de-facto manufacturer.

3.3.4. France – The Pilot Project Shift

France historically enforced absolute statutory bans on reusing any single-use device. However, driven by escalating healthcare costs and green healthcare mandates, it launched a nationwide, 2-year practice-based pilot project. The project permits tightly monitored reuse within select surgical categories to collect data on adverse events and cost-benefit ratios, reflecting a global shift towards pragmatic, evidence-based regulation rather than rigid prohibitions.

4. Actionable Policy Recommendations

The following recommendations establish a structured regulatory framework to transition India from an informal "grey market" for SUDs to a safe, transparent, and economically viable medical device reuse ecosystem.

4.1. A Phased Regulatory Strategy

Implementing a national medical device reuse policy cannot happen overnight. It requires a phased strategy to build institutional capacity, train CSSD technicians, and establish auditing systems:

a. The Ministry of Health and Family Welfare (MoHFW) and the Central Drugs Standard Control Organisation (CDSCO) must jointly constitute a multidisciplinary regulatory committee. This committee must include clinicians, biomedical engineers, infection control experts, legal professionals, and patient representatives to draft a comprehensive "National Policy on Reprocessing of Medical Devices." This body should also be tasked with creating an exhaustive 'Green List' (devices approved for regulated reuse, such as dialyzers and specific electrophysiology catheters) and a 'Red List' (devices strictly banned from reuse, including small-lumen coronary catheters and drug-eluting balloons).

b. The Medical Devices Rules under the Drugs and Cosmetics Act must be amended; 'Reprocessed Single-Use Medical Devices' must be defined; and a distinct legal pathway for 'Licensed Medical Device Reprocessors,' separate from original equipment manufacturers, must be established.

c. Manufacturers must be mandated to scientifically justify the "Single-Use" label. They should be obligated to share clinical data demonstrating why a device cannot be reprocessed, rather than using the label merely to avoid extended clinical trials or liability.

d. The National Accreditation Board for Hospitals & Healthcare Providers (NABH) and the National Accreditation Board for Testing

and Calibration Laboratories (NABL) must develop stringent, standardized guidelines for in-house hospital CSSD.

e. Prohibit informal in-hospital manual reprocessing. Any private or public hospital wishing to engage in SUD reuse must have an automated, certified CSSD that complies with the newly drafted ISO / Bureau of Indian Standards (BIS) benchmarks for medical device reprocessing. Alternatively, hospitals can contract with CDSCO-licensed third-party commercial reprocessing enterprises that assume full product liability for reprocessed devices.

f. Mandate the etching of an unalterable, laser-printed UDI barcode on every high-cost device on the Green List. Every cycle of cleaning, sterilisation, functional testing, and clinical deployment must be recorded in a central database linked to the Material Vigilance Programme of India (MVPI). The software must automatically flag and lock a device from further clinical use once it reaches its pre-validated maximum reuse threshold. Any adverse event, cross-infection, or mechanical failure related to a reprocessed device must be reported within a stipulated timeframe (e.g., 72 hours) to build indigenous data on device efficacy.

g. Leverage the Healthcare Sector Skill Council to standardize training curricula for CSSD technicians across the country, ensuring that personnel understand the precise temperature, pressure, and chemical requirements for safe sterilization.

4.2. Mandatory Institutional SOPs

Hospitals permitted to use reprocessed devices must adhere to a strict, non-negotiable operational protocol within their clinical workflow:

- **Mechanical and Functional Verification**

  Before sterilization, every reprocessed device must undergo automated testing to verify structural integrity. For example, catheters must be pressure-tested for wall strength, and laparoscopic instruments must be checked for insulation defects using electronic scanners to prevent intra-operative burns.

- **Pyrogen and Chemical Residue Clearance**

  Reprocessing protocols must be validated to ensure complete clearance of bacterial endotoxins and removal of residual chemical sterilants (such as ethylene oxide or glutaraldehyde), which can cause tissue damage or systemic toxicity if left in micro-lumens.

- **Chain of Custody**

  To prevent cross-contamination with blood-borne pathogens (such as Hepatitis B, Hepatitis C, and HIV), high-risk semi-critical and critical devices must be restricted to Single-Patient Reuse. Each device must be labelled with the patient's unique medical record number and reused exclusively within that individual's treatment lifecycle, directly mirroring the validated nephrology model for haemodialysis filters.

4.3. Transparency & Informed Consent

To eliminate billing fraud and uphold patient autonomy, the policy must enforce absolute transparency through structured disclosure protocols:

- **Dual-Option Consent Forms**

  Every patient undergoing a procedure involving Green-Listed medical devices must be provided with a dual-option informed consent document in the local vernacular. The document must explicitly present the choice between a brand-new device and a validated, reprocessed device, and detail the safety protocols applied to the latter.

- **Statutory Financial Discounting**

  Hospitals must be legally barred from charging the MRP of a new device for a reprocessed one. The billing system must separate the institutional procedure fee from the device cost. A reprocessed device must be billed at a regulated, fractional cost, ensuring that the financial benefits of reuse are directly passed on to the patient. The Insurance Regulatory and Development Authority of India (IRDAI) must involve insurance companies as key stakeholders to ensure that procedures using certified reprocessed devices are legitimately

covered and reimbursed, thereby preventing fraudulent billing practices.

- **Strict Protection of the Right of Refusal**
  If a patient exercises their right of refusal and opts for a virgin device, the hospital must honour that choice without compromising the quality or availability of clinical care. In government settings operating under fixed caps, if a patient demands a virgin device in violation of the public scheme's standard reuse protocol, a transparent co-payment mechanism must be put in place.

4.4. Legal Safeguards for Acting in Good Faith

A balanced policy must protect healthcare providers from unfair legal exposure. Lawmakers must embed robust legal shields in the regulatory framework:

- **Protection Under Section 49 of BNS (Good Faith Exemption)**
  If a doctor uses a reprocessed device that fully complies with the CDSCO Green List guidelines, adheres to the certified CSSD SOPs, and has a valid informed consent form, any unexpected mechanical failure of the device must be legally classified as an Unavoidable Medical Accident rather than as criminal rashness or professional negligence.
- **Shifting Product Liability**
  Once a hospital or a licensed third-party reprocessor completes validation and signs off on a reprocessed device, the legal liability for any manufacturing defect or material failure shifts entirely from the doctor or hospital to the reprocessing entity. This decouples individual clinical judgment from failures in industrial material processing.

5. Conclusion

The deliberations of the 10th National Convention on Medicine & Law 2025 have established that the reuse of single-use medical devices is an undeniable operational reality across Indian healthcare. Maintaining the current regulatory vacuum does not stop the practice; it merely drives it into an unregulated grey market, exposing patients to avoidable health risks and placing doctors in an unfair legal vulnerability.

The recommendations in this White Paper aim to change medical device reuse from an informal, hidden practice into a highly standardized, transparent, and legally defensible clinical pathway. By establishing clear statutory guidelines under the CDSCO, drawing an empirical line between permissible and non-permissible devices, mandating automated infrastructure, and enforcing absolute financial and communicative transparency with the patient, India can pioneer a unique healthcare model.

This framework balances the twin principles of affordability and uncompromised patient safety. It will enable the nation to dramatically expand access to advanced tertiary healthcare, curb the rise of toxic biomedical plastic waste, preserve public and private insurance ecosystems, and legally empower healthcare professionals. The transition from a "conspiracy of silence" to a framework of institutional integrity is the only viable path to building a healthier, safer India, ensuring that the fundamental right to life is protected without compromising patient safety, clinical efficacy, or affordability.

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