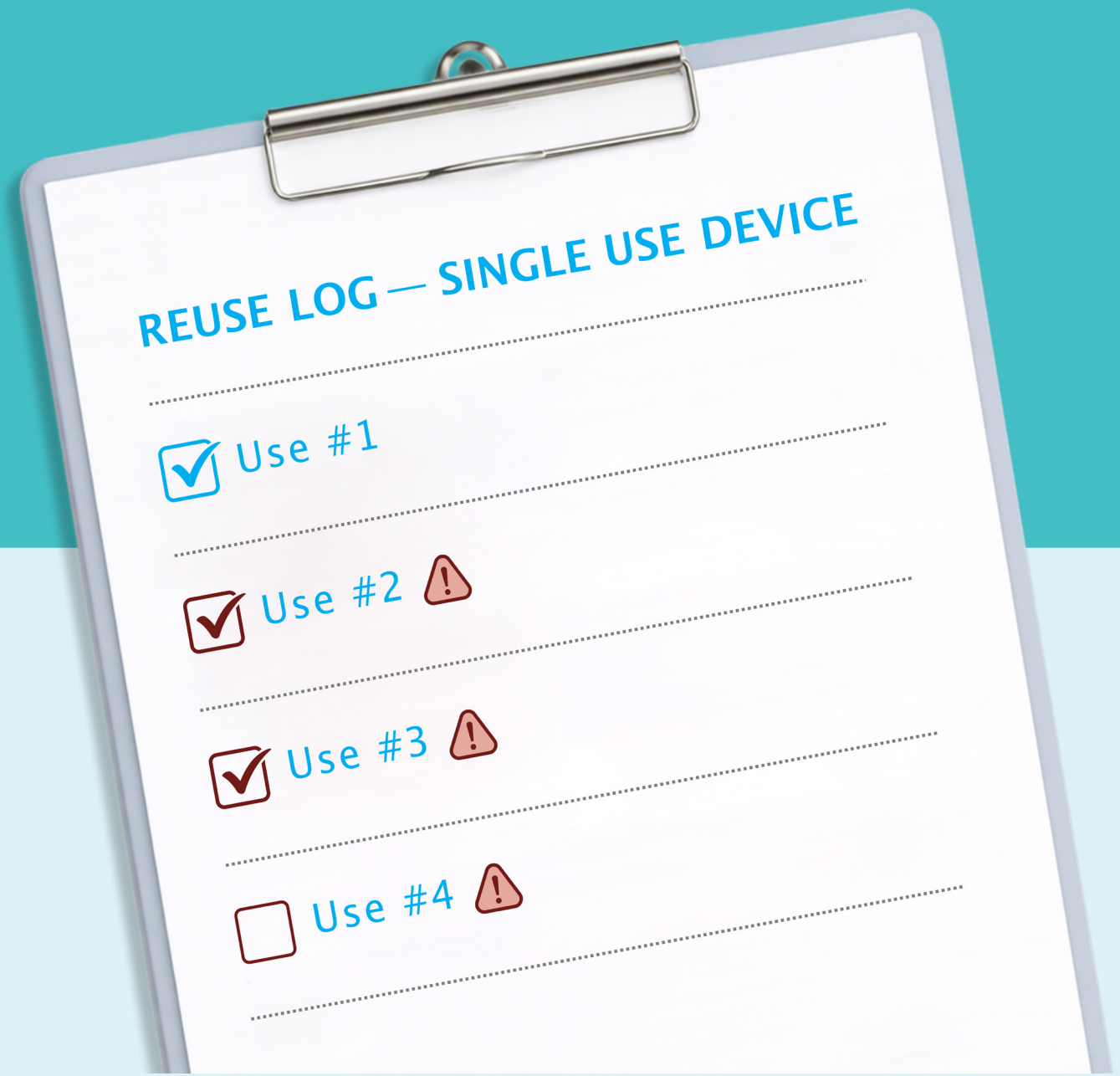
MTaI
MEDICAL TECHNOLOGY ASSOCIATION OF INDIA

POLICY WHITEPAPER

APRIL 2026

Reuse of Single-Use Medical Devices in India

Patient Safety, Ethics, Sustainability, and Regulatory Accountability



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Foreword

At the heart of every healthcare system lies a moral contract — the imperative to protect human life with diligence, evidence, and integrity. When this contract is strained by ambiguity - whether in policy, practice, or incentives - the fallout extends well beyond operational inefficiency — it erodes trust, deepens inequity, and unsettles the very foundations of clinical care.

The practice of reusing devices explicitly labelled for single use is one such ambiguity. On its surface, it may appear as a pragmatic response to cost pressures and supply constraints. Yet when examined through the lenses of patient safety, ethical responsibility, and systemic coherence, it reveals a confluence of risks and contradictions that demand clear thinking and decisive action.

This white paper does not merely catalogue concerns; it challenges us to face a deeper question: can a health system that accommodates uncertainty in matters of basic safety still claim to honour its duty to patients and the public? The answer, implicit in the evidence and arguments that follow is, that policies and practices must align with clinical concern and ethical imperatives.

By combining empirical analysis with regulatory insight and international perspective, this paper seeks to elevate the discourse beyond technicality to one of shared purpose.

It is my hope that readers- policymakers, practitioners, and industry leaders alike, will engage with these ideas not as abstract propositions but as catalysts for meaningful reform.

Pavan Choudary
Chairman & Director General
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Executive Summary

Reuse of medical devices labelled for single use has become an established, though largely informal, practice in parts of India's healthcare system. It occurs at the intersection of rising device dependence, affordability constraints, sustainability considerations, and commercial incentives within both public and private healthcare delivery. While reuse is often justified on grounds of cost containment and environmental benefit, it is typically undertaken outside a nationally regulated framework for validation, oversight, disclosure, and accountability.

At the same time, India continues to face a significant burden of hospital-acquired infections (HAIs). In a system where sterilization and infection-control capacity is improving but remains uneven across facilities, any added dependence on re-sterilization/ reprocessing, particularly of devices not designed or validated for multiple cycles creates avoidable uncertainty around sterility assurance, cross-infection, and predictable device performance.

This white paper argues that routine reuse of SUDs in India should be approached with caution. In the absence of a dedicated regulatory pathway, validated reprocessing standards, system-wide sterility assurance, and mandatory patient transparency, reuse introduces avoidable risks to patient safety, ethical practice, and system credibility.

Drawing on evidence from infection surveillance, sterilisation audits, material science, ethics, environmental life-cycle research, and regulatory analysis, the paper concludes that reuse cannot be assumed to be safe, ethical, economical, or environmentally beneficial under current conditions. If reuse is to be considered at all, it must transition from informal, hospital-level coping practice to a regulated exception, governed by clear national standards and enforceable accountability mechanisms. Such a mechanism is not present in India today and hence the reuse of medical devices intended for single use must be completely stopped.

Introduction

India's healthcare system delivers increasingly complex, device-intensive care at an unprecedented scale. Advances in interventional cardiology, orthopaedics, oncology, and critical care have expanded access to life-saving interventions, but they have also increased reliance on high-value disposable medical devices, where providers operate within constrained public budgets, price-sensitive private markets, and a system where out-of-pocket expenditure remains substantial.

Within this context, reuse of devices labelled for single use has emerged as a practical response. However, pragmatism alone cannot serve as a policy justification when patient safety, informed consent, and system integrity are at stake. Reuse of SUDs is not merely a procurement decision; it is a safety-critical practice with implications for infection control, device performance, ethics, and liability.

This white paper examines reuse of SUDs through six lenses:

1. Economic and commercial drivers
2. System readiness and infection risk
3. Device performance and material integrity
4. Ethics and regulation
5. Environmental Considerations
6. Regulatory Landscape

Implications of Reuse of Single-Use Medical Devices

A Tug-of-War: Balancing Economics, Ethics and Patient Care

Drivers of Reuse: Cost Pressure and Commercial Incentives

Reuse of SUDs in India is frequently framed as an affordability measure. In public healthcare facilities, reuse is often rationalised as a means of stretching limited budgets and expanding access to essential procedures. These pressures are real and deserve acknowledgement. However, affordability alone does not explain the persistence of reuse across diverse healthcare settings. In private hospitals, reuse can also function as a commercial strategy, allowing institutions to reduce procurement costs while maintaining procedure pricing. Regulatory investigations have documented instances where reused devices were billed at prices close to those of new devices, weakening the claim that reuse necessarily benefits patients.

For example, a Maharashtra Food and Drug Administration (FDA) investigation described reuse of cardiovascular catheters while patients were charged as much as 77% of the maximum retail price (MRP), suggesting weak cost pass through and undermining the affordability rationale where transparency is absent.

Even where billing is fair, safe reuse is not cost-neutral. High-assurance reprocessing requires validated cleaning and sterilisation, functional integrity verification where appropriate, traceability systems, staff training, and a quality management approach that can reliably demonstrate consistent outcomes. International evidence also cautions against assuming that procurement savings automatically translate into net savings.

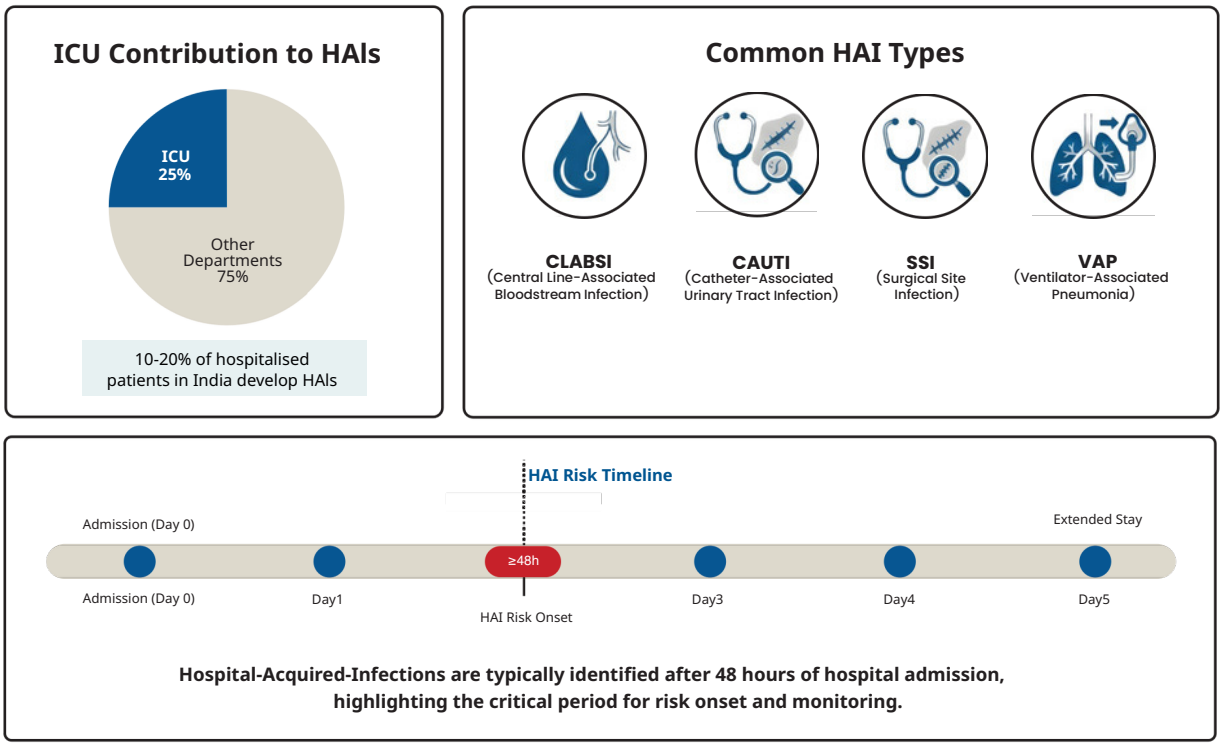
A Health Research Board (HRB) systematic review and meta-analysis on reprocessing of SUDs found that reprocessing resulted in cost savings, but marginal savings diminished with subsequent reprocessing cycles. Depending on the SUD, reprocessing reduces global warming impacts but may exacerbate human health impacts. Reviewers had little confidence in the effects reported across all outcome types.

When complications, infections, longer hospital stays, and repeat procedures are considered, poorly controlled reuse can erase apparent savings, and, in some cases, cost more than using new devices. Framing reuse solely as an affordability response risks granting hospitals excessive latitude while overlooking transparency, pricing governance, and accountability.

Importantly, reuse in India is not a single practice but a spectrum. In some facilities, reuse occurs under internal protocols with defined cycle limits and access to sterile-processing systems. In others, reuse is informal, weakly documented, or inadequately validated. In the absence of authorised third-party reprocessors and clear regulatory pathways, variability becomes the defining feature resulting in unequal safety assurance for patients.

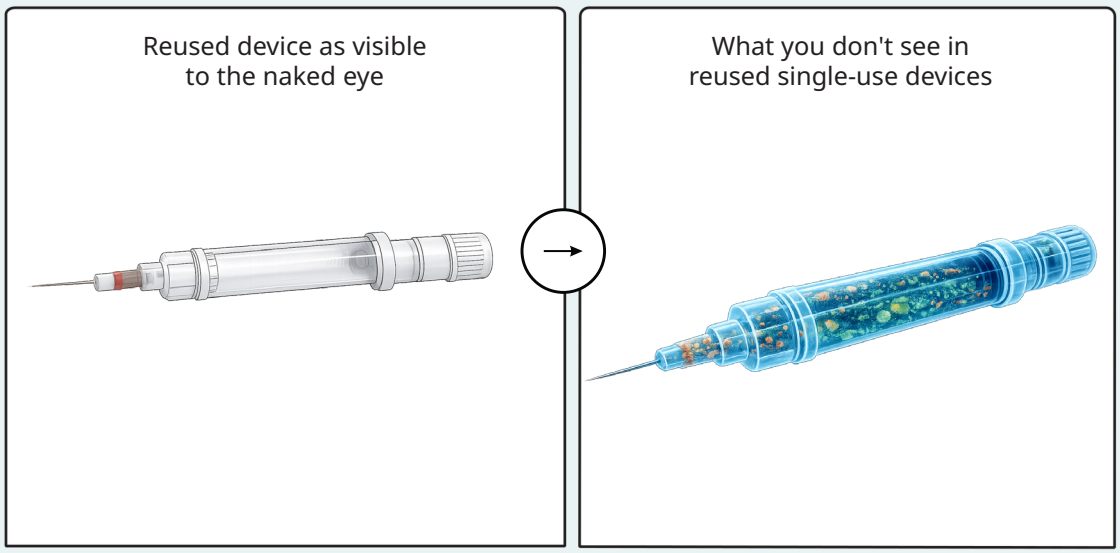
Infection Burden and Its Relevance to SUD Reuse

Infection-control science highlights how reusing SUDs can increase patient risk when reprocessing controls are inconsistent. Because many SUDs have lumens and complex internal geometries, inadequate cleaning and sterilisation can leave residual organic soil and microbial contamination in channels that are difficult to access, reducing the effectiveness of subsequent disinfection/sterilisation and enabling pathogen transmission. Simulated-use testing of a triple-lumen SUD showed that standard manual cleaning and automated washing through ports could still leave contamination in a lumen, underscoring that "reprocessability" must be demonstrated through validated methods, not assumed.



This risk is compounded by system readiness. While India's sterile-processing capacity is improving, implementation remains uneven across facilities. National guidance emphasises well-designed Central Sterile Services Departments (CSSDs), unidirectional workflows, validated equipment, appropriate use of indicators for sterilisation monitoring, and disciplined documentation.

Audit observations also suggest scope for strengthening consistency on the ground; for example, a Comptroller and Auditor General (CAG) audit of healthcare services in Uttar Pradesh noted variations in the availability of chemical sterilisation in some test-checked hospitals, alongside gaps in maintenance and validation practices for sterilisation equipment. In this context, reuse of devices labelled for single use imposes a higher bar than routine reprocessing of validated reusable instruments. Where infrastructure, monitoring, and documentation are variable, reuse introduces additional infection risk and unpredictable assurance. Outcomes become facility-dependent rather than system-controlled precisely the condition under which reuse becomes hardest to defend on patient-safety and accountability grounds.



Disclaimer:

Conceptual illustration for awareness purposes, not an actual clinical image

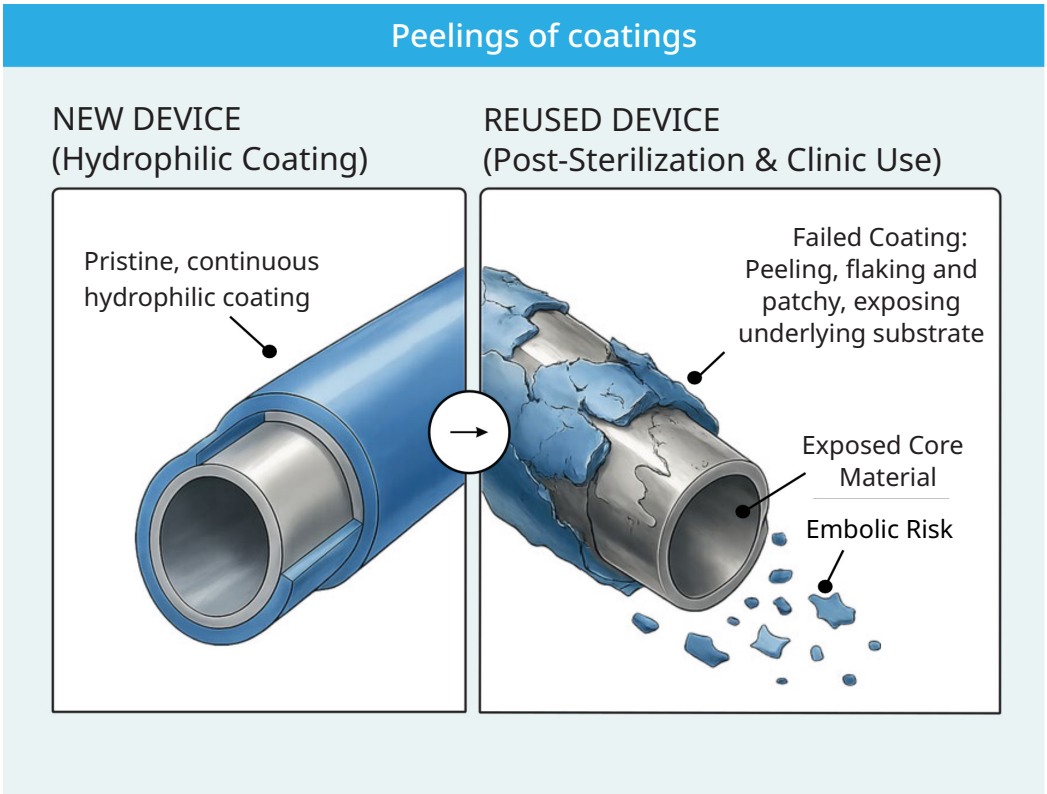
Material Degradation and Device Failure

Single-use devices are engineered for one clinical episode, after which the manufacturer's assurance of safety and performance no longer applies. Their materials, coatings, joints, and structural tolerances are selected on the assumption that they will not undergo repeated cleaning and sterilisation. Repeated exposure to cleaning chemistries, sterilants, and high-temperature steam cycles can alter polymer behaviour, weaken interfaces, and change mechanical properties in ways that are not detectable through routine visual inspection or simple handling checks.

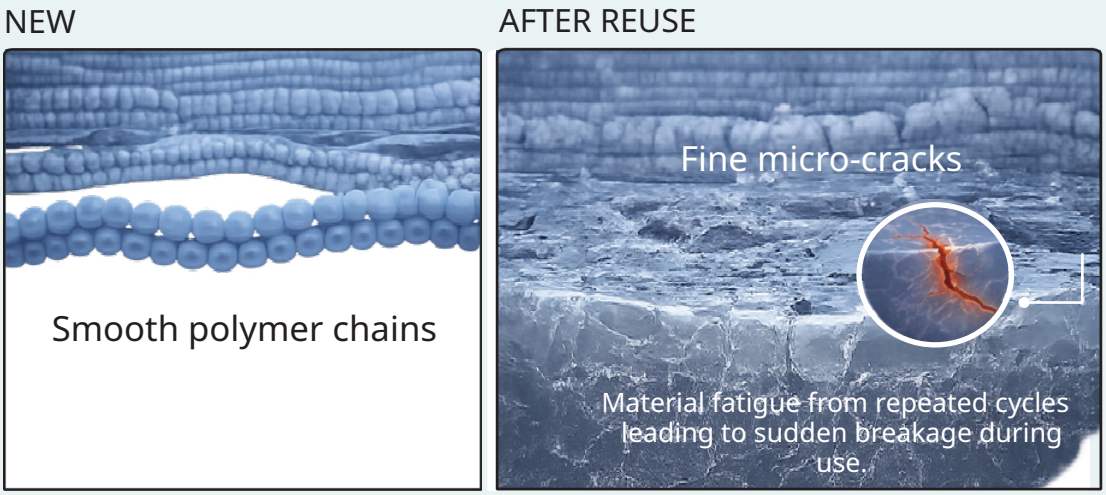
Experimental evidence supports this concern. In a study of a spring-like clip made from medical grade polyetheretherketone (PEEK) sterilised repeatedly by autoclave (121 °C, 30 min; up to 100 cycles), the authors reported a ~20% reduction in compression force after 30 cycles and a ~6% reduction in lateral dimension after 50 cycles, demonstrating that meaningful performance loss can accumulate across reprocessing cycles even in materials considered robust for medical applications. The implication is straightforward: As mechanical performance subtly declines with repeated use and reprocessing, a device may no longer function the way its original design used to. For complex devices with lumens and fine channels, residual soil and biofilm may persist and accumulate across cycles, creating hidden failure modes that compromise function and predictability.

These findings reinforce a core point that is often underweighted in cost-driven debates: the risk of SUD reuse is not limited to sterility. Even if a reused device is nominally sterilised, it may no longer meet the manufacturer-validated performance specifications that underpin predictable clinical use. In settings where reuse occurs without device-specific validation of cleaning, sterilisation, and post-reprocessing performance, malfunction and in-procedure failure become foreseeable hazards rather than rare anomalies.

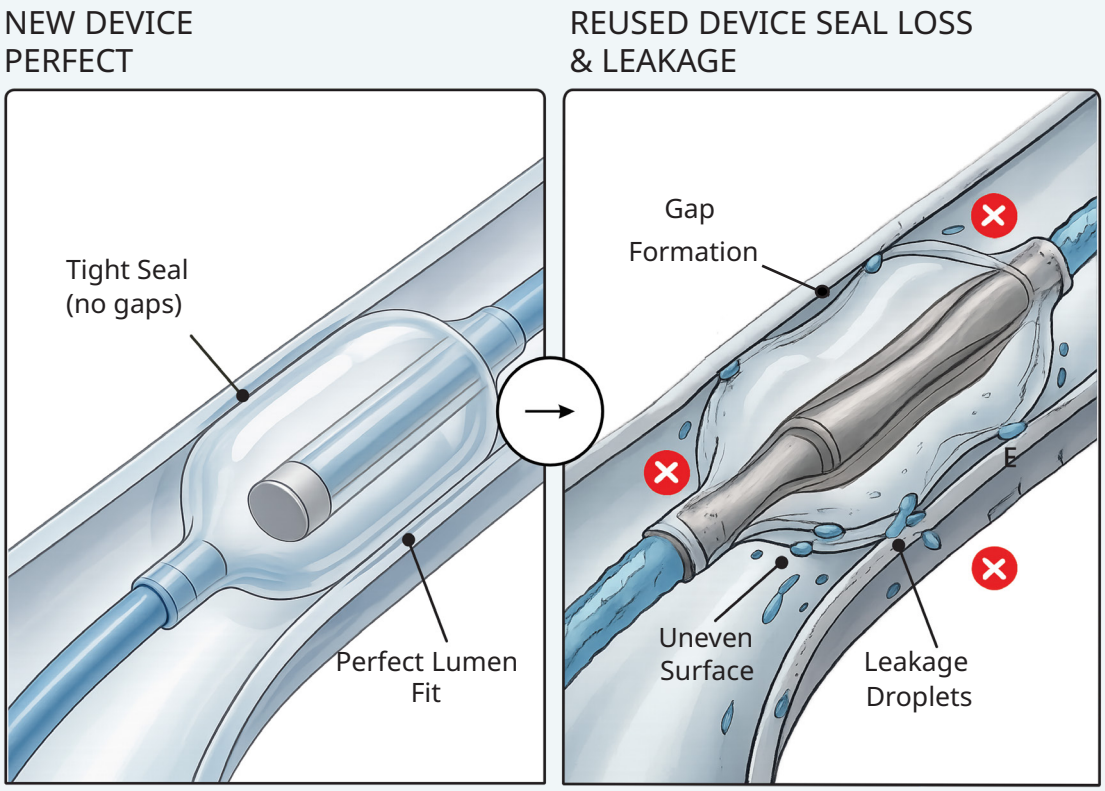
Material degradation can mainly be seen as:



Damage in Surface Structure



Shape Deformation



Dimensional changes from degradation lead to leakage / failure

Ethical Considerations: Transparency, Consent, and Asymmetry

The ethical challenge posed by informal reuse is rooted in asymmetry. Patients are often unaware that a device labelled for single use has been reused. They cannot meaningfully consent to risks they are not informed about, nor can they assess trade-offs between cost and safety when pricing does not transparently reflect reuse. Without disclosure, traceability, and fair pricing, reuse shifts from a pragmatic compromise to an ethical breach. Transparency and informed consent are not optional safeguards; they are prerequisites for legitimacy in modern healthcare.

Three asymmetries define the ethical fault line of informal reuse:

Environmental Considerations

Environmental sustainability is increasingly cited as a justification for reusing SUDs. Life-cycle assessments from regulated systems suggest that manufacturing and logistics account for a large share of a device's environmental footprint, and that controlled reprocessing can reduce waste and emissions.

However, environmental benefit is conditional. Sustainability gains assume tightly regulated reprocessing, validated cleaning and sterilisation, functional testing, and traceability. Where compliance is inconsistent, reuse may shift environmental burden to energy-intensive sterilisation, chemical use, and poorly managed biomedical waste streams.

Sustainability, therefore, cannot justify informal reuse. It supports only regulated, audited reprocessing systems.

Regulatory Landscape

India's Medical Devices Rules, 2017 rely on the manufacturer's declared "intended use," which is based on the information the manufacturer provides through labelling, instructions for use, and promotional material. While devices intended for single use must be labelled accordingly, the regulatory framework does not provide a dedicated pathway for reprocessing such devices. There is no nationally defined eligibility criterion for reuse, no validation standards, no licensing regime for third-party reprocessors, no mandated reuse limits, and no clear allocation of liability in the event of harm.

As a result, reuse persists in a regulatory grey zone — neither explicitly prohibited nor meaningfully governed.

Globally where reuse is permitted, it is typically channelled through regulated third-party reprocessors operating under standards comparable to manufacturing controls. In India, reuse largely occurs within hospitals under variable protocols, limiting oversight and accountability.

Policy Implications and Recommendations

Immediate Position: Reuse Must Stop in the Absence of Policy

In the absence of a national policy governing reuse or reprocessing, current practice lacks uniform standards for validation, oversight, traceability, disclosure, and liability. Reuse should therefore be explicitly stopped with immediate effect.

Regulatory Mandate: Removing Ambiguity and Ensuring Uniform Compliance

To operationalise this position, regulators should issue a clear mandate prohibiting reuse of devices labelled for single use, anchored in manufacturer labelling and Instructions for Use, and applicable uniformly across public and private facilities. Enforcement should include inspection, documentation, and accountability mechanisms.

Future Pathway: Conditional, Regulated Reprocessing-If Considered

If, at a future point, India chooses to permit reprocessing of select SUDs, it should be treated as a new, tightly regulated activity, not as a continuation of current informal practice.

Any such pathway must begin with a risk-based determination of eligibility, clearly distinguishing which device categories may be considered and which are excluded.

Reprocessing should be permitted only under validated standards equivalent to manufacturer-level assurance, including cleaning, sterilisation, and functional integrity testing. It should occur through licensed entities operating under audited quality systems, with clear assignment of responsibility and liability. Traceability and transparency must be non-negotiable. Devices should be trackable across reprocessing cycles, and patients must be informed and able to provide meaningful consent. Where reprocessing is justified on affordability grounds, pricing governance must ensure that economic benefits are transparently passed on and not retained through opaque billing practices.

Policy-End State

Until such a framework exists and demonstrates consistent, system-wide assurance, reuse of SUDs should not be tolerated as routine practice. If reprocessing is permitted when regulatory framework is created, it must function as a regulated exception- designed to prove safety, protect patient rights, and enforce accountability, rather than as an informal workaround to systemic pressures.

Conclusion

Reuse of devices labelled for single use persists because it is economically tempting and operationally convenient. However, in a system with a high baseline burden of healthcare-associated infections and uneven sterility assurance, informal reuse remains clinically and ethically indefensible. The immediate requirement is regulatory clarity: reuse must stop. If reprocessing is ever permitted, it must be validated, auditable, transparent to patients, and accountable by design.

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About Medical Technology Association of India (MTaI)

Medical Technology Association of India (MTaI pronounced Em-tai) is a not-for-profit organisation duly registered under sub-section (2) of section 7 of the Companies Act, 2013 and Rule 8 of the Companies (Incorporation) Rules, 2014. MTaI is an association of research-based medical technology companies that have made significant investments in India, by setting up a large number of R&D centres and manufacturing plants. It represents a wide spectrum of the medical devices and equipment industry, bringing global experience in innovation and manufacturing. With a constant focus on the three hallmarks of healthcare: Quality, Consistency and Patient Safety, MTaI strives to be a responsible voice of the industry and is committed to improving access to affordable and quality healthcare for patients. MTaI collaborates with the government, healthcare professionals and other stakeholders to support innovative solutions enabled by the medical technology industry, while also working to create space for companies commensurate with their contribution to improving healthcare in India. MTaI seeks to partner with the Government of India in setting a roadmap for growth of the medical devices sector by attracting larger investments, enabling technology upgradation, and supporting knowledge dissemination in the provider space, including through initiatives that strengthen FDI and the Government's Make in India and Design in India vision.

Credits:

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