

# Medical-Grade Materials in Menstrual Cups: Biodegradation, Safety, and Allergic Reaction

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**Abstract:** Menstrual cups have become popular as a greener option compared to disposable menstrual products. The safety and biocompatibility of medical-grade materials employed in these products e.g., medical-grade silicone, thermoplastic elastomers (TPEs), natural rubber continue to be of main concern. This paper assesses the potential for biodegradation, safety profile, and risk of allergic reaction of these materials, especially against international medical standards (e.g., ISO, FDA, EU regulations). Whereas medical-grade silicone reflects excellent stability, low toxicity, and limited allergenicity, TPEs and natural rubber are associated with increased risks through chemical additives and protein residues, respectively. Accelerated aging and in vitro cytotoxicity experiments indicate that silicone-based cups show excellent long-term safety. Rare instances of hypersensitivity reactions do, however, indicate the necessity of better material standardization and allergen marking. This review highlights the necessity of strict material testing for safeguarding users' safety while pressing for continued research in biodegradable options without sacrificing biocompatibility.

**Keywords:** Medical-Grade silicone; Thermoplastic Elastomers (TPE); Natural Rubber Latex; Biodegradable Polymers; Medical Device Materials; Biocompatibility; Cytotoxicity; Vaginal Microbiome; Biofilm Formation; Latex Hypersensitivity; Syndrome; Allergic Contact Dermatitis; Toxic Shock Syndrome.

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## I. INTRODUCTION

The increasing focus on sustainable menstrual management has prompted heightened use of menstrual cups as a green alternative for reusable products such as tampons and pads(1). These appliances, usually constructed from medical-grade silicone, thermoplastic elastomers (TPEs), or natural rubber, are economical and environmentally friendly because they minimize waste and costs in the long run(1,2).

Yet, for all their merits, there are serious questions about the biodegradability, long-term safety, and even possible allergic reactions of the materials used to make them(3).

Medical-grade silicone, the most common material, is generally considered safe for its chemical stability, its hypoallergenic nature, and conformity to international medical device regulations (FDA, 2020; ISO 10993). Nevertheless, differences in polymer formulations, remaining

manufacturing by products (e.g., platinum catalysts, siloxanes), and breakdown through multiple use cycles can present unforeseen health hazards. Other materials, like TPEs and natural rubber, bring other issues, like possible leaching of plasticizers and latex protein-induced sensitivities(4).

Though regulatory agencies like the FDA and EU MDR categorize menstrual cups as medical devices, which call for biocompatibility testing (cytotoxicity, sensitization, irritation), there is limited overall long-term biodegradation research and real-world data regarding allergic reactions. In addition, varying labelling of material composition and possible allergens hinders educated consumer decisions, especially for those with sensitivities(3).

This review critically assesses the medical-grade material's potential for biodegradation, safety profile, and allergenic hazard in menstrual cups, integrating current *in vitro*, clinical, and regulatory information(5). Through the determination of critical research gaps and material-related issues, this review will inform future research, enhance industry standards, and provide assurance that the transition to sustainable menstrual products does not undermine user safety(6).

#### ➤ *Background on Menstrual Cups*

Menstrual cups have undergone vast improvement since their original patent during the 1930s, and today they are a green solution for disposable menstrual products due to increased environmental concerns. In contrast to disposable tampons and pads, which form the majority of global plastic waste, current reusable menstrual cups provide an environmental solution lasting 5-bacterial10 years(7). Their use has escalated, especially in developed nations, although challenges related to availability remain in low-resource environments. The rising market value necessitates proper assessment of the materials of construction used in their production, specifically with regards to their biodegradation potential, safety profiles, and allergenic risks. Modern menstrual cups are primarily composed of medical-grade silicone, thermoplastic elastomers (TPEs), or natural rubber latex, each with their merits and drawbacks(8).

Most commonly used is medical-grade silicone, which is popular for its chemical stability, tensile strength, and accordance with global biocompatibility standards (e.g., ISO 10993, FDA Class II). Nevertheless, differences in polymer compositions, residual additives (e.g., catalysts, plasticizers), and sterilization methods can impact long-term safety(9). TPEs, although budget-friendly, have been less thoroughly investigated, which creates worries regarding conceivable chemical leaching and environment persistence. Natural rubber latex, while seldom utilized today, has well documented allergy concerns, and transparency regarding the material used in product labels is key(10). Another under-emphasized but critical point is the biodegradability of these materials. Whilst silicone is inert and durable, environmental persistence is its challenge, in that it is not easily biodegradable. TPEs, sold as more environmentally friendly than conventional plastics, can still feed into micro plastic contamination. Biodegradable alternatives are still in their infancy, which highlights the demand for development in

material science to bring menstrual cup manufacturing in line with circular economy approaches(11). From a safety standpoint, menstrual cup side effects are uncommon but may consist of mechanical irritation, chemical sensitivity, and allergic reactions. While regulatory environments require biocompatibility testing, existing gaps exist to determine long-term exposure effects, cumulative material degradation, and uniform allergen labelling(12). Resolving these issues is necessary to determine user safety without eroding the environmental advantages that make menstrual cups an appealing substitute(5).

#### ➤ *Evolution of Reusable Menstrual Products*

Though the history of menstrual cups identifies their environmental benefits and material issues, tremendous gaps exist in addressing the entire gamut of sustainability and safety issues. This has prompted the development of a wider array of reusable menstrual products, each with singular material issues and challenges relating to biodegradation, safety, and allergy potential (7).

The expanding market for reusable menstrual devices, such as cups, discs, and absorbent undergarments, mirrors a shift in paradigm for managing feminine hygiene. It has been fuelled by consumers' mounting environmental awareness, and research has indicated that a menstrual cup can substitute for 2,000-3,000 disposable items throughout its lifespan(13). Change has introduced concerns over material safety, especially long-term exposure to medical-grade polymers and environmental end points(14).

Medical-grade silicone continues to be the standard for reusable menstrual products because of its proven biocompatibility and chemical stability(2). Growing popularity of menstrual discs has extended uses of this material further, albeit with differences in thickness and flexibility that could influence patterns of degradation. At the same time, innovations in alternative materials for reusable pads and period underwear have added new factors into play about textile treatments, antimicrobial agents, and absorbent layers that could present different biodegradation and sensitization issues(15).

The reusable menstrual product revolution has also revealed gaps in existing regulatory schemes. Whereas single-use items are subject to strict disposal requirements, the extended lifecycle of reusable counterparts presents various material exposure situations that necessitate reassessment of safety thresholds(16). This applies especially to products where multiple materials are mixed (e.g., silicone with plastic stems or metal rings), where interfacial degradation and material interactions become critical issues to consider(17).

Consumer education has become an essential component in the proper adoption of such products. Research has shown that failure to clean properly or excessive use over recommended periods can hasten material degradation or enhance microbial attachment, which could be at the expense of user safety or product lifespan. The above revelations point to the imperative of more explicit guides on material maintenance and replacement timetables(18).

The expansion of the market has also brought to light differences in material quality, some companies using non-medical grade silicones or unspecified "soft plastics" to save costs. This inconsistency makes it difficult for consumers to attempt to balance safety standards with affordability, and reinforces the need for greater clarity in labelling material composition(19). With the reusable menstrual product industry expanding, the emphasis on medical-grade materials has gained momentum, with producers pushing boundaries through new technologies such as biodegradable thermoplastic elastomers and plant-based silicones. These innovations, though, need to be thoroughly assessed against stringent biocompatibility testing to guard against endangering safety through attempts at sustainability(20).

This development with menstrual care products showcases that while reusability is a response to most environmental issues, it brings new aspects to the material safety discussion that are worth carefully examining - especially concerning long-term material integrity, cumulative effects of exposure, and end-of-life disposal(21).

➤ *Objectives of the Study*

The study will thoroughly examine the safety, environmental compatibility, and biocompatibility of medical-grade materials like silicone, thermoplastic elastomers (TPE), and natural rubber latex employed in menstrual cups. It will describe their physicochemical characterization, examine their biodegradability in various environments (landfill, soil, compost), and study their long-term ecological implications, such as the production of microplastics and lifecycle sustainability. Moreover, the study explores biocompatibility through a look into the

interaction of such materials with the vaginal microbiome, pH equilibrium, and possible harms like cytotoxicity, biofilm, and Toxic Shock Syndrome (TSS). Allergic sensitivities, such as sensitivities to silicone, protein allergy to latex, and hypersensitivities to TPE, are also given attention through clinical case histories and immune profiles. The research also examines existing regulatory guidelines (ISO 10993, FDA guidelines) and detects gaps in testing protocols, certification, and post-market monitoring. It also discusses user-related elements like global material preference trends, misinformation, and the impact of marketing on consumer decisions. Lastly, the study identifies core challenges such as inadequate long-term clinical data and the imperative for innovation in the form of intelligent polymers and completely biodegradable options and offers actionable suggestions for manufacturers, policymakers, and consumers to enhance menstrual cup safety and sustainability.

**II. MATERIALS EMPLOYED IN MENSTRUAL CUPS: COMPOSITION, SAFETY, AND PERFORMANCE**

Menstrual cups are largely made of medical-grade materials that are required to pass strict safety requirements for extended intravaginal use. Among the most used materials medical-grade silicone, thermoplastic elastomers (TPE), and natural rubber latex the three have unique chemical structures determining their durability, biocompatibility, and environmental footprint. Understanding these material properties is crucial for consumers, healthcare professionals, and policymakers to ensure informed decisions for menstrual health products(22).

Table 1 Types of Menstrual Cups

Key properties	 <b>Medical-Grade Silicone</b>	 <b>Natural Rubber Latex</b>	 <b>Thermoplastic Elastomer</b>
<b>Composition</b>	Synthetic polymer	Natural polymer obtained from <i>Hevea brasiliensis</i>	Plastic & rubber polymers
<b>Flexibility</b>	Highly Flexible	Flexible & Elastic	Flexible & Firm
<b>Biocompatibility</b>	Excellent Biocompatibility	Inherently Biocompatible	Moderate Biocompatibility
<b>Biodegradability</b>	Non-biodegradable	Slightly Biodegradable	Biodegradable
<b>Cost</b>	Expensive	Cheaper	Less expensive
<b>Allergic Risks</b>	May cause Irritation	Itching, Dryness, Redness	Hypoallergenic
<b>Usage of Duration</b>	Upto 12 hrs	Upto 12 hrs	Upto 12 hrs
<b>Durability</b>	5–10 years	2-5 years	3-5 years
<b>Sterilization Resistance</b>	Excellent	Poor	Good
<b>Environmental impact</b>	Smaller Carbon footprint	Deforestation	Potential microplastic emissions
<b>Recyclability</b>	Non-recyclable	Non-recyclable	Recyclable
<b>Regulatory approval (FDA/CE)</b>	Widely approved and tested	Limited due to allergic risks	Must be medical-grade for approval

➤ *Medical-Grade Silicone: The Gold Standard for Safety and Durability*

Medical-grade silicone represents the pinnacle of material science for menstrual cup applications, offering an

exceptional combination of biocompatibility, durability, and user safety. This high-performance elastomer is synthesized from dimethylsiloxane polymers through a carefully controlled manufacturing process that eliminates impurities

and volatile compounds(23). Unlike industrial-grade silicone variants, medical-grade formulations undergo exhaustive purification to remove residual catalysts (such as platinum) and low-molecular-weight siloxanes that could potentially trigger cytotoxic reactions or local tissue irritation(5).

Its three-dimensional, cross-linked molecular structure lends high elasticity with dimensional stability such that the cup is able to withstand repeated use cycles without losing its shape. Its molecular architecture also produces an inherent non-porous surface (pore sizes <1  $\mu\text{m}$ ), clinically important in reducing bacterial adhesion and biofilm production - an important criterion in TSS prevention. Substantial clinical trials have shown that silicone cups preserve normal vaginal pH (3.8-4.5) without interfering with the fine balance of lactobacilli populations and hence promoting vaginal microbiome integrity and minimizing dysbiosis or mucosal irritation risks(24). Practically, the thermal stability of medical-grade silicone (withstanding temperatures up to 120°C) allows for repeated sterilization by boiling, steam, and chemical disinfection. This feature effectively prolongs the product's functional life span to 5-10 years under care, which is economically and environmentally beneficial over disposable options(25).

Although generally well-accepted, controversy does surround the issue of potential sensitivity reactions. Recent medical literature attests that properly formulated medical silicone is not an initiator of Type I (IgE-mediated) allergic reactions. Individual case reports have documented contact dermatitis-like reactions, which were presumably due to residual manufacturing additives and not the silicone polymer itself. Regulators globally, the FDA and EMA, assert that medical-grade silicone poses little allergenic risk when produced to accepted standards(26).

#### ➤ *Thermoplastic Elastomers (TPE): Balancing Affordability and Performance*

Thermoplastic elastomers (TPE) have become a cost-efficient substitute for silicone in the manufacture of menstrual cups, with unique benefits and drawbacks(20).

Typically, these materials consist of styrene block copolymers (SBS or SEBS) which have rubber-like elasticity coupled with thermoplastic process ability without the requirement for vulcanization. Although this renders TPE cups softer and more flexible overall than silicone, it also leads to lower thermal resistance - most TPE formulations start to break down at 60-80°C, so sterilization is limited to gentle chemical disinfectants instead of boiling(27). One important consideration with TPE is its micro porosity, with surface pores usually 10-50  $\mu\text{m}$ . This structural feature gives one pause in terms of bacterial entrapment and the possibility of biofilm development. Nonetheless, one should consider that existing epidemiological evidence does not support a causal link between TPE cup utilization and rising TSS incidence, and that good hygiene habits can reliably overcome this risk(28). Quality of material widely differs between TPE formulations, with lower-quality types possibly including plasticizers (e.g., phthalates) that will leach out over time. Manufacturers adhere to strict regulations such as EU REACH and FDA 21 CFR to assure safety, but the fact

that there is no universal medical device classification for TPE cups leaves standards of quality varying in the marketplace. From an environmental standpoint, TPE offers a mixed picture. Whereas some newer bio-based versions of TPE assert partial biodegradability, traditional petroleum-based versions remain in the environment, slowly breaking down into micro plastics. Lifecycle assessment research demonstrates that production of TPE has a greater carbon footprint than medical silicone based on energy-intensive polymerization reactions and petrochemical-based sourcing.(29)

#### ➤ *Natural Rubber Latex: Waning Option with Enduring Allergy Risks*

Natural rubber latex from the *Hevea brasiliensis* tree has historical importance as the first material used in ancient menstrual cups (see the 1930s "Daintette" model). Due to its high tensile strength (15-25 MPa) and its theoretically biodegradable nature, it was a desirable early option. That said, the high allergenic nature of the material has resulted in its virtual elimination from contemporary menstrual products(30).

The fundamental reason is latex's intricate protein composition, specifically the Hev b group of allergens (Hev b 1, Hev b 3, etc.). Despite thorough processing and washing, residual proteins (usually  $\leq 50 \mu\text{g/g}$ ) are still effective at inducing intense IgE-mediated responses in sensitized individuals. Epidemiological evidence calculates that roughly 1.2% of the general population demonstrates latex hypersensitivity, with increased frequency among healthcare professionals and those with spina bifida. In addition to allergic issues, latex's inherent micro porosity allows for bacterial colonization, requiring antimicrobial treatments that can itself trigger irritation. Although latex products illustrate comparatively quick degradation under composting conditions (average 1-2 years), these clinical safety concerns relegated natural rubber latex to specialty uses in the menstrual product industry. Modern substitutes have generally replaced latex, although it still appears in some specialty items for consumers without sensitivity issues.

The material's failure is a case study in weighing environmental advantage against clinical risk, as it reveals the intricate trade-offs inherent in menstrual product material choice. Contemporary material science continues to pursue replacements that marry latex's biodegradability with better safety profiles, though no ideal replacement has yet appeared(30,31).

### III. BIODEGRADATION AND ENVIRONMENTAL EFFECTS OF MENSTRUAL CUP MATERIALS

The environmental sustainability of menstrual cups has become an important issue in the worldwide transition to green feminine hygiene products. Although reusable cups provide substantial waste reduction advantages over disposable tampons and pads, their long-term environmental consequences differ widely based on the materials involved in their manufacture.(5) Each of the three major materials - medical-grade silicone, thermoplastic elastomers (TPE), and

natural rubber latex - carries unique biodegradation profiles, environmental persistence properties, and possible ecological impacts that are deserving of serious scrutiny. This section presents a systematic look at how these materials develop across their life cycle, from intravaginal application to eventual disposal, with specific eye on their bio stability, degradation routes in various environments, micro plastic production potential, and relative environmental profiles(32).

➤ *Biostability versus Biodegradability in Intravaginal Use*

The perfect material for menstrual cups should achieve a fine balance between bio stability under use and ultimate biodegradability on disposal. Medical-grade silicone is superior in bio stability, retaining its shape and chemical inertness over years of use. This remarkable stability is a result of its cross-linked polymer structure that is resistant to degradation from the natural vaginal fluid, which generally has a pH of 3.8 to 4.5. The non-porous nature of the material inhibits biofilm formation and bacterial adhesion, two key factors in preventing toxic shock syndrome (TSS) and ensuring vaginal health(33). Notably, the bio stability of silicone ensures that it will not release micro plastics or toxic chemicals when used, though the same feature makes it resistant to biodegradation in the environment. The average lifespan of a silicone menstrual cup is 5 to 10 years if taken care of, and it is among the most long-lasting options(34).

Thermoplastic elastomers (TPE) have another profile, providing moderate bio stability and one that differs highly depending upon formulation quality. In contrast to the thermoset nature of silicone, the linear polymer backbone of TPE makes it more prone to progressive degradation from repeated heat stress during sterilization, chemical reactions with vaginal secretions, and mechanical fatigue from normal use. Although superior-grade medical TPE formulations exhibit sufficient stability for menstrual cup use, lesser-quality types can progressively leach plasticizers like phthalates. The inherent porosity of the material, with surface voids usually between 10-50 micrometres, further complicates concerns about bacterial retention unless thoroughly cleaned. These points add up to a generally more abbreviated usable life of 2-5 years for TPE cups compared to silicone cups.

Natural rubber latex sits in a curious middle ground along the stability-biodegradability scale. As a naturally occurring substance, latex has biodegradability inherent in it that makes it theoretically more environmental than man-made equivalent alternatives(5). Yet the same makes it less bio stable to use. The protein-based nature of the material breaks down progressively in the vagina environment, likely resulting in loss of elasticity, porosity increase, and diminished potency with time. The majority of commercial latex cups are submitted to chemical stabilization treatments, which extend their active lifespan to about 1-3 years, but at the cost of hindering the natural biodegradability of the material as well. Latex has also well-documented allergenic potential through residual proteins that can cause IgE-mediated hypersensitivity responses in vulnerable individuals, which again restricts its applications in modern menstrual products(35).

➤ *Degradation Pathways in Different Environments*

Knowledge of menstrual cup material behaviour in various disposal environments is important for evaluating their full environmental footprint. Within soil ecosystems, the three materials exhibit significantly different patterns of degradation. Medical-grade silicone exhibits impressive persistence, being resistant to biodegradation but gradually breaking down into small pieces by mechanical weathering over many decades. Although these silicone fragments fail to release toxic chemicals, their persistence is a concern with respect to accumulation over very long timescales within terrestrial environments(20). TPE acts even more adversely in the earth, degrading into micro plastics that can last centuries and potentially leaching plasticizers and additives into the environment. Natural rubber latex has the best soil degradation profile, with raw latex degrading in 1-5 years under optimal conditions of sufficient moisture and microbial action. But chemical treatments to which commercial latex products are subjected can greatly retard this process(36). Landfill sites have extremely difficult conditions for material breakdown in their anaerobic environments. Under these oxygen-lacking environments, silicone is in effect unchanged over hundreds of years, as the microbial activity used to break it down is largely unavailable. TPE also is resistant to breakdown in landfill settings, resulting in long-term plastic pollution and possibly the release of methane as additives progressively degrade. Latex shows somewhat better performance in landfill conditions than the synthetic alternatives, but its decomposition in anaerobic environments produces methane - a potent greenhouse gas with 25 times the global warming potential of carbon dioxide over a 100-year period. This methane generation partially offsets latex's biodegradability advantage in landfill scenarios(30,35).

Composting systems offer the most favourable conditions for environmentally benign degradation, particularly for natural rubber latex(30). In properly managed compost facilities with proper aeration and microbial action, untreated latex will break down fully in 6-24 months. Most commercially sold latex cups, though, are accompanied by stabilizers and vulcanizing agents that greatly retard this action. Silicone is relatively unaffected by composting activities, although some high-temperature industrial composting systems can hasten its physical breakdown. Traditional TPE is not compostable at all, although some companies have started creating bio-based TPE formulations with partial composability at certain conditions claims(37).

Seawater environments pose distinctive challenges to menstrual cup material breakdown. Silicone, though resistant in seawater, does not leach toxic chemicals nor exhibit notable bioaccumulation potential. TPE also presents the highest marine hazard, quickly breaking down into micro plastics that can adsorb persistent organic contaminants from seawater prior to entering the marine food web. Latex degrades faster than conventional materials in the marine environment but can still take months to years to fully degrade, during which period it can cause entanglement hazards to marine organisms. The natural origin of the material makes it usually less toxic to aquatic life than

petroleum-derived alternatives, but chemical additives in finished latex products can undo this benefit(38).

➤ *Micro Plastic Issues and Long-Term Eco Toxicity*

The potential for menstrual cup materials to cause micro plastic pollution has been recognized as a major environmental issue. Medical-grade silicone poses the lowest risk here, as degradation creates inert particles instead of actual micro plastics. These silicone particles do not share the same ability to adsorb environmental pollutants or interfere with endocrine systems as petroleum-derived micro plastics. Recent studies show no indication of silicone particles bio accumulating in marine life or causing detectable ecological damage at environmental levels(39).

TPE, on the other hand, is a considerable source of micro plastic pollution because it breaks down into resilient particles that will not further degrade. These micro plastics derived from TPE not only sink into the ecosystem but also act as vectors for the transport of hydrophobic contaminants such as PCBs and DDT. The small particle size allows them to be taken up by a variety of organisms with potential for trophic transfer through food chains. Long-term Eco toxicological impacts of this contamination are still poorly understood but could involve physical obstructive, chemical toxicity, and endocrine interference in target species(40).

Natural rubber latex is in the intermediate category of micro plastic formation. Although the material does degrade into small particles, those tend to be biodegradable and do not remain in the environment for extended periods like synthetic micro plastics. Chemically treated latex does have the potential to emit stabilized fragments that are not fully broken down, and certain additives can show Eco toxicity(30,35). The proteinaceous nature of latex particles makes them more susceptible to microbial attack than petroleum-based plastics, but the speed of degradation depends heavily on environmental conditions and processing history(30).

Beyond micro plastic generation, the long-term Eco toxicity of menstrual cup materials requires consideration. Silicone's chemical inertness translates to minimal ecological toxicity, though its physical presence in ecosystems may have undocumented effects(32).TPE's capacity for leaching plasticizers, stabilizers, and other additives is of greater concern, especially in aquatic ecosystems where these chemicals could interfere with endocrine function in wildlife. Latex's natural basis predicts lesser inherent toxicity, but vulcanization chemicals, antioxidants, and other processing chemicals can alter this profile. The fate of these additives and degradation products in the environment is an area in need of further investigation(40).

➤ *Lifecycle Comparison: Silicone vs. TPE vs. Latex*

An extensive lifecycle study of menstrual cup materials needs to account for several stages from raw material extraction to end-of-life waste. The production stage exposes

significant differences in environmental impact sources(41). Medical-grade silicone starts with silica (from sand) and oil-based precursors, which demand high energy inputs for processing but gain from the material's unusually long lifespan. TPE manufacture is completely dependent on petrochemical feedstock's, perpetuating fossil fuel use and resultant greenhouse gas emissions. Natural rubber latex is derived from renewable rubber tree plantations, but the monoculture systems usually result in deforestation, pesticide application, and other ecological trade-offs which counter some of the material's sustainability benefits(42).

The production stage continues to distinguish between the materials. Silicone production encompasses energy- and material-intensive processes such as polymerization, curing, and purification, but these effects are distributed over a product life twice that of TPE equivalents. TPE production takes less energy than silicone production but produces a product of briefer useful life and longer environmental persistence. Latex manufacture consists of accumulation of natural rubber latex sap followed by diverse stabilization and moulding processes that differ significantly in their energy needs and patterns of chemical utilization(30).The usage phase emphasizes the strengths of silicone in durability and very low maintenance needs. One silicone cup can substitute for thousands of single-use menstrual products over a 5-10 year lifespan, reducing overall waste generation radically. TPE cups need replacement more often (every 2-5 years), raising their overall resource use. Latex cups are in the middle but are limited by allergenic issues that limit their market penetration(39).End-of-life disposal is a situation of complicated trade-offs among the materials. Silicone's stability against degradation means it will not release toxic breakdown products but leads to long-term waste build up. There are some specialized recycling initiatives for silicone products, although participation is limited. TPE's lack of recyclability and persistence as micro plastics renders it the worst choice from an end-of-life viewpoint. Latex has theoretical biodegradability benefits only if products get to suitable composting facilities and not landfills(35).When considering the complete lifecycle, medical-grade silicone emerges as the most environmentally responsible choice for most users, despite its petroleum origins. The material's exceptional durability and stability outweigh its production impacts when considered over a full decade of use. TPE's reduced lifespan and micro plastic formation render it generally less sustainable, while latex's biodegradability benefits are tempered by its reduced functional lifespan and restricted market uptake on account of allergenic issues. Emerging innovations in bio-based silicones, advancements in latex processing, and TPE recycling technologies might change the balance in the future, but the available evidence currently favours silicone as the most sustainable mainstream choice(30,39).

#### IV. BIOCOMPATIBILITY AND VAGINAL SAFETY

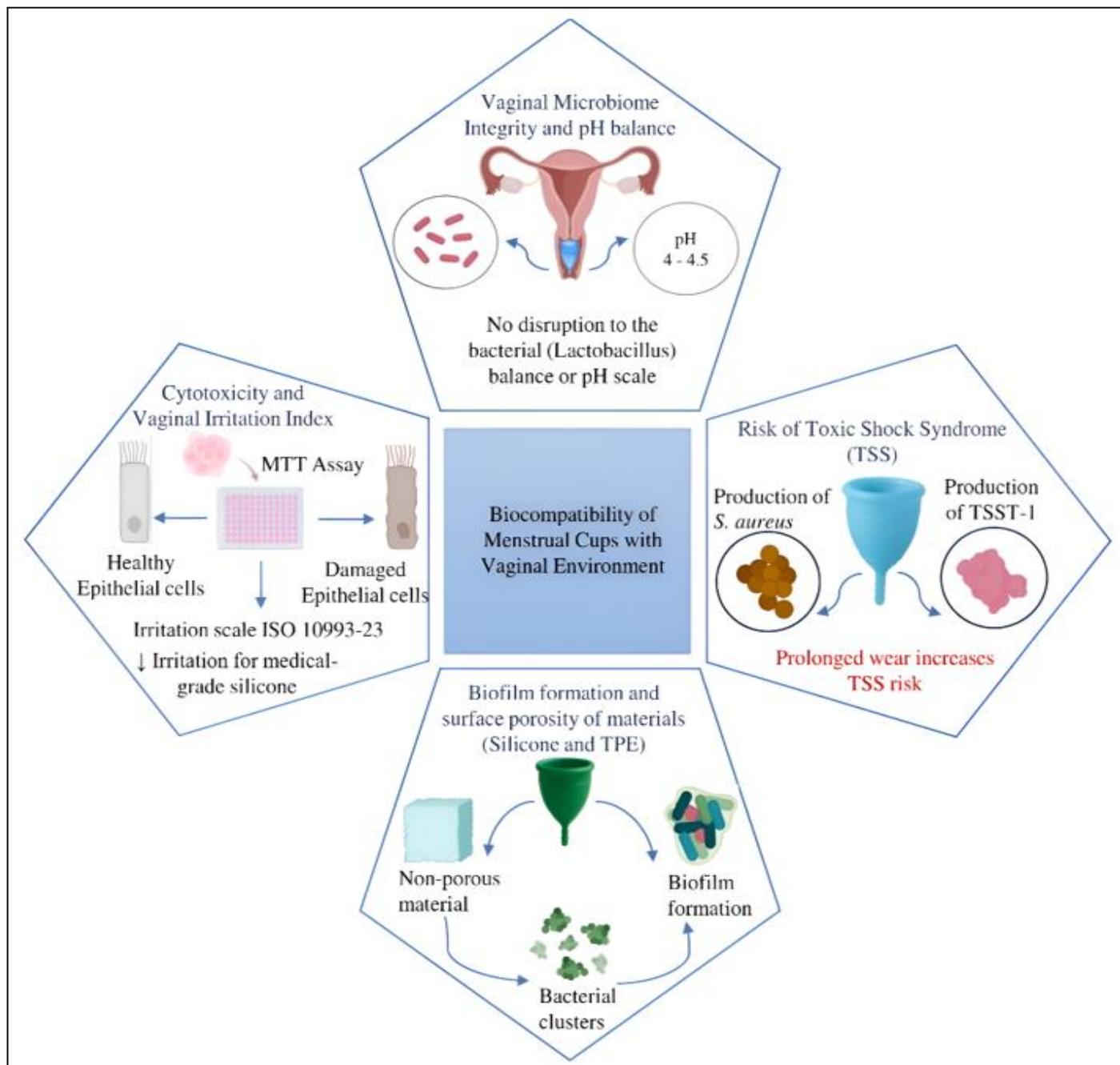


Fig 1 Biocompatibility of Menstrual Cups with Vaginal Environment

Silicone used in medical applications, and which is the main material for the majority of contemporary menstrual cups, undergoes rigorous biocompatibility tests to ensure suitability for extended use within the vagina(2). Such tests analyse a range of factors such as inertness of the material, irritation potential, and general compatibility with sensitive vaginal tissues. The use of medical-grade silicone is intentional since it has to conform to rigorous regulatory requirements by bodies such as the FDA and ISO to allow it to come into repeated contact with mucous membranes over long periods. In addition to raw material safety, scientists also study how these items interact with the vaginal environment, especially in the areas of microbiome balance, risk of infection, and possibility of causing allergic reactions(12). High-quality silicone's non-porous quality ensures fluid absorption prevention with structural stability, forming a protective layer between accumulated menstrual

fluid and vaginal walls. This feature is essential as it ensures that the material never becomes a breeding ground for bacteria while at the same time preventing interference with natural vaginal secretions that help in tissue health. Manufacturers utilize a number of curing processes, with platinum-cured silicone being the best available in terms of its high purity and lack of potentially irritating by products. Other considerations for safety are that the cup should be flexible and shaped to fit over vaginal walls without exerting excessive pressure or friction that might result in microscopic tears or irritation. The aggregate findings of clinical studies and material science experiments resoundingly attest to the safety profile of correctly produced medical-grade silicone menstrual cups when used as instructed, rendering them a safe choice for menstrual management(43).

➤ *Vaginal Microbiome Integrity and pH Balance*

The vaginal microbiome is an intricate and fragile ecosystem in which *Lactobacillus* species are crucial for sustaining health through lactic acid production and pH balance (generally 3.8-4.5). This acidic environment provides a natural barrier against pathogenic microorganisms that might lead to infection like bacterial vaginosis or yeast infections. Medical-grade silicone menstrual cups exhibit higher biocompatibility in this sense than conventional menstrual products. In contrast to tampons that absorb not only menstrual flow but also vaginal secretions, silicone cups retain fluid without shedding protective mucus or disrupting microbial communities(44).

➤ *Risk of Toxic Shock Syndrome (TSS)*

The association of menstrual products and Toxic Shock Syndrome has preoccupied the medical literature since the 1980s, when highly absorbent tampons were identified as the cause of TSS outbreaks. Although menstrual cups offer a decidedly different risk profile, their possibility of being associated with TSS needs to be examined very closely in terms of microbial dynamics. Menstrual-related TSS pathogenesis includes growth of toxin-producing *Staphylococcus aureus* strains in stationary menstrual blood, followed by absorption of the toxins through vaginal mucosal surfaces. The non-absorbent nature of medical-grade silicone provides a much altered environment from that of tampons since it does not dry out vaginal tissues or produce the low-oxygen environment conducive to staphylococcal toxin production(45). Epidemiological evidence shows that incidence of TSS among cup users continues to be extremely rare, with case reports being unusually uncommon in the literature.. Antimicrobial-treated cups have been launched by some manufacturers, although studies are still being conducted on their effectiveness as well as possible influence on vaginal flora. Medical experts worldwide advise hand washing thoroughly prior to insertion/removal, not wearing cups all the time for more than 12 hours, and adherence to manufacturer sterilization protocols. These measures, along with the material's natural resistance to bacterial adhesion, render TSS a highly improbable complication with correct menstrual cup use, although healthcare professionals emphasize that vigilance over symptoms (acute high fever, rash, dizziness) still applies to all users of menstrual products(46,47).

➤ *Biofilm Formation and Surface Porosity of Materials*

Menstrual product biofilm formation is a serious issue since the organized bacterial populations have increased resistance to cleaning and disinfection. Medical-grade silicone surface features render inherent benefits against biofilm formation over other menstrual product material. Smooth, non-porous surface of high-quality silicone reduces the small-scale surface area where bacteria can adhere and start developing protective extracellular matrices(2). Scanning electron microscopy examinations comparing various menstrual cup materials have consistently revealed that medical-grade silicone retains superior surface integrity even through multiple use cycles, while thermoplastic

elastomers and latex alternatives tend to form micro-fissures that support bacterial adherence. A study had assayed bacterial adhesion patterns on different menstrual cup materials and determined that medical-grade silicone samples had up to 80% lower levels of bacterial colonization than porous samples after equal exposure times(48). While long-term use always results in some surface wear, microscopic scratches may develop from cleaning practices, fingernail exposure during insertion/removal, or storage environments. These tiny flaws, though imperceptible to the naked eye, can serve as reservoirs for microbial build up over time. The manufacturers respond to this with material engineering, some of them using ultra-smooth surface coatings or antimicrobial additives (though the latter are controversial due to their possible ecological effects). Accurate maintenance procedures dramatically prolong material life and safety - specialists advise using pH-neutral, fragrance-free cleaners instead of abrasive soaps that could break down silicone, steering clear of scouring cleansing devices, and keeping cups in open containers instead of airtight spaces that could harbor microbe growth. The optimal replacement schedule of 2-5 years is an economic-material integrity compromise, but users need to monitor cups regularly for surface deterioration signs such as cloudiness, stickiness, or odour retention that could be an indicator of microscopic damage threatening hygiene(49,50).

➤ *Cytotoxicity and Vaginal Irritation Index*

Evaluation of menstrual cup materials' cytotoxic potential is under strict international standards (ISO 10993) testing cellular reactions to long-term material exposure. Medical-grade silicone repeatedly exhibits strong biocompatibility in these tests, with no signs of cell toxicity or significant inflammatory reactions in reproducible assays. The chemical inertness of the material avoids leach-off of compounds that could interfere with cellular function or stimulate immune response, an important consideration for products that remain in contact with sensitive mucosal tissues for hours on end. Nonetheless, all silicone products are not produced to reach the same levels of purity - final material safety is greatly affected by the curing process. Platinum-cured silicone, made using an addition-curing process, has practically no residual byproducts, while peroxide-cured versions could still contain traces of curing agents that may prove irritating to extremely sensitive people. Clinical evidence from dermatology research indicates that true silicone allergies are extremely uncommon, with reported reactions in most cases due to other ingredients such as pigments, plasticizers, or processing residues and not the silicone polymer. A study in Contact Dermatitis reviewed all reported cases of mucosal reactions to silicone and found fewer than 20 confirmed cases globally, almost all related to non-medical grade products or industrial silicone use. For individuals with multiple chemical sensitivities or documented material allergies, manufacturers increasingly give detailed material disclosures and some obtain third-party testing certification. Vaginal irritation potential is also influenced by physical aspects - very firm cups may induce pressure irritation, while those with rough seams or edges could create friction

points. Modern manufacturing processes now enable smooth designs and graduated firmness that conform to vaginal walls without overbearing pressure. Continuing research in material science investigates further upgraded formulations with plant-based silicones or surface treatments that can potentially decrease any slight irritation potential, although existing medical-grade silicone already sets a very high safety standard for use in the vagina. and Allergic Reactions(2,50).

## V. ALLERGIC AND HYPERSENSITIVITY REACTIONS

As menstrual cup popularity increases as a green alternative to disposable feminine products, there have been concerns raised about allergic and hypersensitivity reactions. Although medical-grade silicone cups are safe overall, it is important for users and healthcare providers alike to understand these infrequent but significant reactions(3).

### ➤ *Silicone Sensitivities: Myth or Fact?*

The controversy surrounding silicone sensitivity continues to be one of the most controversial issues in feminine hygiene product safety. Medical-grade silicone, or polydimethylsiloxane (PDMS), has a remarkable safety profile based on centuries of application in medical implants and devices. Its polymer structure, with alternating oxygen and silicon atoms and methyl side chains, exhibits excellent stability against degradation and low interaction with biological systems. This built-in chemical stability is the basis of the superior biocompatibility of silicone and the reason why the majority of well-established menstrual cup manufacturers prefer the material.

Notwithstanding its widespread perceived safety, isolated case reports of unpleasant reactions still keep consumers worried. Medical literature offers an intriguing paradox: whereas millions of women have been using silicone menstrual cups uneventfully, some minority, albeit vocal, complain of symptoms from mild irritation to severe dermatitis. A systematic review of reported cases shows fewer than 30 confirmed reports of silicone-related contact dermatitis in all medical device uses, with only a few specifically associated with menstrual products. This very low rate of incidence strongly indicates that actual silicone allergies are highly unusual events and not typical reactions.

Upon closer inspection, the majority of reported "silicone allergies" are actually reactions to residual manufacturing chemicals and not to the silicone polymer itself. Peroxide curing procedures, employed in certain production techniques, can deposit minute residues of active by products that might provoke irritant or allergic reactions in sensitive tissues. Platinum-cured silicone, made by an alternative chemical process, avoids this problem because it deposits no reactive residues, and thus it is the first choice when known chemical sensitivities exist. Furthermore, pigments, plasticizers, or other additives that are sometimes included in menstrual cup designs can be unrecognized allergens(9).

The clinical presentation of presumed silicone reactions usually takes a type IV delayed hypersensitivity pattern, and symptoms occur 48-72 hours following exposure. The involved individual may present with localized erythema, pruritus, or eczematous change at the site of contact. Diagnosis has to be done carefully through meticulous patch testing employing standardized extracts of silicone and scrupulous exclusion of other possible allergens. Most cases once diagnosed as silicone sensitivity later turn out to be reactions to accompanying substances such as dyes, fragrances, or cleaning agents used together with the devices.

For consumers concerned about potential silicone sensitivity, several precautionary measures can help mitigate risks. Choosing platinum-cured silicone products from reputable manufacturers significantly reduces exposure to potential irritants. Performing a simple patch test by wearing the cup inside the elbow for 24-48 hours before vaginal use can help identify potential reactors. Opting for undyed, fragrance-free models eliminates two common sources of allergic reactions unrelated to silicone itself(51).

### ➤ *Latex Allergy and the role of Protein Residues*

While controversy over silicone sensitivity rages on, the danger of latex in menstrual products is well-documented and potentially severe. The medical community identifies natural rubber latex as a major allergen with estimated prevalence ranging from 1-6% in the general population. While most quality manufacturers have made the shift to latex-free options, some cheaper alternatives and older models may still use natural rubber materials, which carry high risks for sensitized individuals(52).

The immunological underpinnings of latex allergy are multifaceted interactions between the immune system and certain proteins of natural rubber. The major allergens are Hevein (Hev b 6.02), rubber elongation factor (Hev b 1), and a variety of other structurally sophisticated antigens. These proteins may cause immediate hypersensitivity responses based on IgE antibodies, and their clinical manifestations vary from straightforward localized symptoms to potentially life-threatening anaphylaxis. Severity of reaction is usually related to the exposure route, with mucosal contact (as with menstrual products) usually producing more severe responses than cutaneous exposure(53). The clinical relevance of latex allergy in feminine products is also heightened by the latex-fruit syndrome phenomenon. This cross-reactivity takes place when the sensitized person allergic to latex proteins experience allergic reactions to structurally related proteins in some fruits, including bananas, kiwis, avocados, and chestnuts. The similar structural motifs shared between latex allergens and these plant proteins can create new, often severe, allergic reactions in sensitized patients. For menstrual users with latex sensitivity, even the smallest amount of natural rubber is apt to cause symptoms. The advent of thermoplastic elastomers (TPEs) as substitutes has only made matters worse, since certain formulations of TPE consist in part of latex-derived materials or display sufficient structural resemblance to cause cross-reactions in

extremely sensitive individuals. This emphasizes the value of complete material disclosure by producers and meticulous label reading on the part of consumers. Contemporary advice for latex-allergic patients highlights a number of major precautions. Foremost among these is the choice of medical-grade silicone products from credible manufacturers with open labelling practices, and this majorly lowers risk. Buyers need to specifically search for clear "latex-free" certifications rather than depending on vague advertising claims. Patients with a history of extreme reactions need to be in standard allergy precautions, such as keeping epinephrine on hand and discussing their allergy

with close contacts. The medical profession continues to support universal avoidance of latex in intimate health products, considering the presence of safer alternatives and the severity of harm from accidental exposure. Many countries' regulatory authorities have imposed tougher labelling requirements for medical devices containing latex, although enforcement remains uneven across regions and product classes. Consumer education continues to be essential in avoiding accidental exposures, especially with the menstrual product market extending to more affordable products that could cut corners on material quality(54).

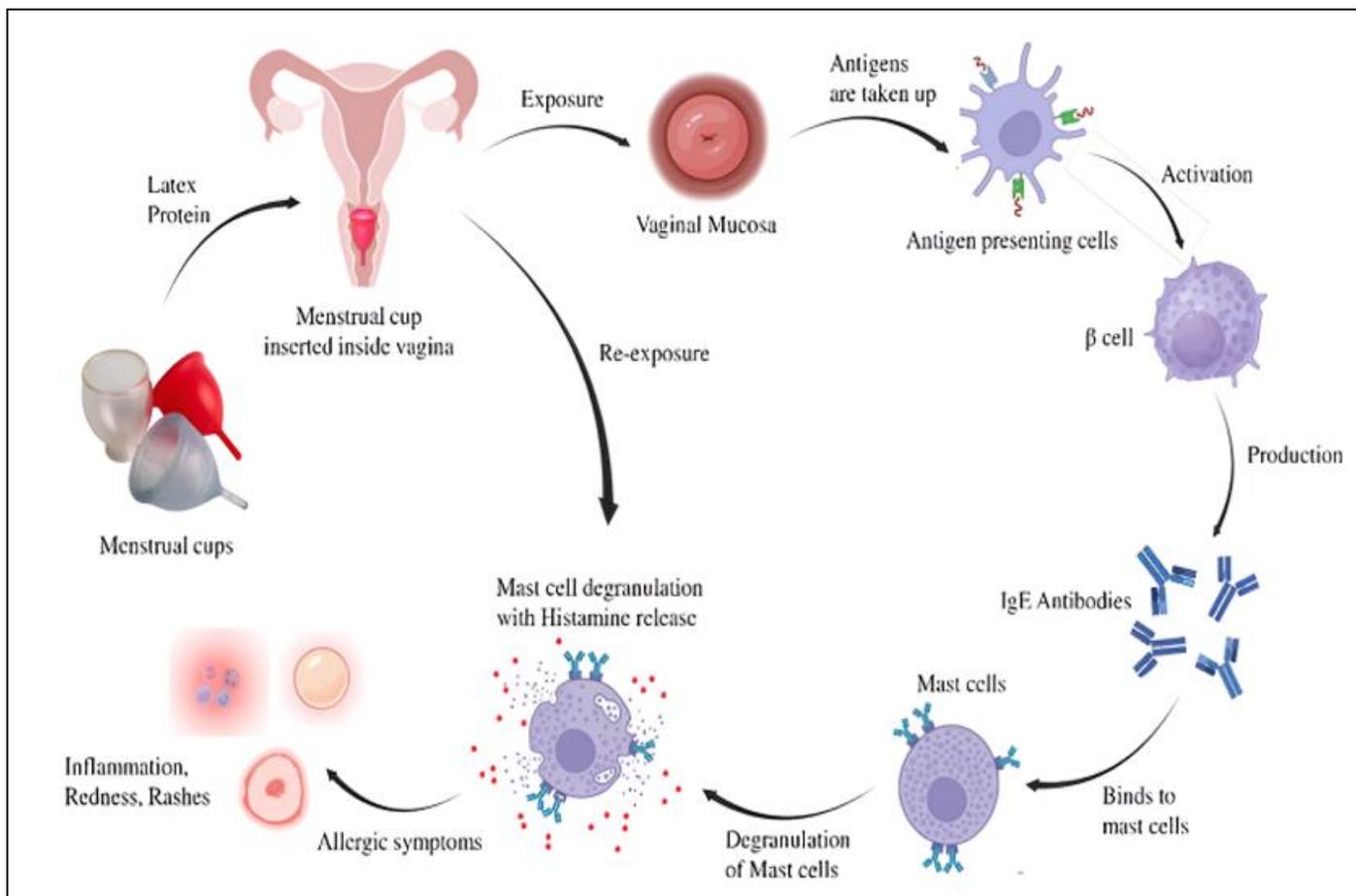


Fig 2 Latex Allergy and the Role of Protein Residues

➤ *Immune Response Profiling in Long-Term Users*

As menstrual cups move from being specialty items to standard feminine care products, their long-term immunological effects are more vital to understand. Recent longitudinal research has started to provide a comprehensive picture of how long-term use influences vaginal immunology and microbiome stability. The data emerging so far offers reassuring safety information for the product but highlights key considerations for best use.

Global immunological profiling of long-term menstrual cup users identifies preservation of normal vaginal mucosa integrity and immune function. Central immunological markers, such as secretory IgA concentrations and cytokine profiles, are found to remain within normal limits even after several years of

uninterrupted use. The vaginal microbiome, an essential element of the local immune defence, is found to be remarkably stable in long-term cup users, retaining its signature *Lactobacillus* dominance without any signs of silicone-induced dysbiosis(54,55).

Advanced flow cytometry analyses of mucosal immune cells reveal normal profiles of T cell subsets and antigen-presenting cells in long-term users. The results indicate no evidence of silicone-specific immune activation or chronic inflammatory reactions. The maintained balance between effector and regulatory immune cells is a sign that medical-grade silicone retains its non-immunogenic nature even after extended mucosal contact. Notably, some research has indicated possible advantages of menstrual cup usage over conventional products. By bypassing the drying

action and micro trauma caused by tampon use, cups can potentially maintain a more normally physiological vaginal environment. This might theoretically serve natural defences by protecting mucosal integrity and minimizing the chance for pathogen penetration. Researchers point out, however, that these possible benefits entirely rest upon correct product choice and usage practices.

The accumulation of microscopic surface irregularities with time is a significant consideration for extended users. Although high-quality medical-grade silicone resists remarkable retention of its smooth surface properties, all materials will eventually develop some level of wear with frequent use and cleaning. These microscopic flaws would, theoretically, potentially harbor bacteria or generate areas of friction, though existing evidence indicates this mostly impacts infection risk rather than immune response.

Ideal long-term utilization involves monitoring a number of crucial considerations. Frequent examination of the cup for indication of surface deterioration allows for detection of when replacement is warranted. The majority of producers suggest replacement every 2-5 years, although actual life is influenced by usage frequency and sanitation strategies. Good sanitation procedures, such as frequent sterilization and proper cleaning between uses, maintain product integrity and vaginal well-being.

Current research efforts are investigating next-generation materials with improved surface properties and possible immune-modulating properties. Nanoscale surface modification might further inhibit bacterial adhesion while preserving biocompatibility. Certain experimental models involve subtle texture patterns aimed at facilitating beneficial microbiome maintenance, although such innovations are still in the embryonic stage of development(56).

## VI. REGULATORY CURRENT STANDARDS AND TESTING REGIMENS FOR MENSTRUAL CUPS

Menstrual cups are medical devices in the majority of countries, with strict safety and performance standards that must be met. Country-specific regulatory systems differ, but fundamental testing protocols are aimed at material safety, biocompatibility, durability, and sterilization. The following is a categorization of significant regulations and required testing across the world(2).

### ➤ *ISO 10993 and FDA Regulations.*

Regulatory standards for menstrual cups are largely guided by two main frameworks: the International Organization for Standardization's ISO 10993 standards and those of the U.S. Food and Drug Administration (FDA) guidelines. These all-encompassing frameworks set highly stringent requirements for assessing the biocompatibility of medical devices coming into contact with mucosal membranes, including menstrual cups. ISO 10993, under the "Biological evaluation of medical devices" series, presents a systematic framework for evaluating possible risks from

material components, Part 1 being dedicated to testing and evaluation within a process of risk management(2,7). Menstrual cups are classified by the FDA as Class II medical devices in the US, in which premarket notification via the 510(k) process is necessary except under exemption. Both organizations focus on a tiered testing strategy that takes into account contact nature and duration, with menstrual cups generally being placed under the "limited exposure" category ( $\leq 24$  hours) for the majority of tests but "prolonged exposure" ( $> 24$  hours to  $\leq 30$  days) for repeat use assessment. Recent revisions of these standards have increasingly focused on chemical characterization according to ISO 10993-18, so that manufacturers must identify and quantify all extractable and leachable materials that might migrate from the device under use conditions encountered in the clinic. This change is a response to increased awareness that comprehensive material knowledge is the basis for valid biological risk assessment. The European Union's Medical Device Regulation (EU MDR 2017/745) places additional demands via Annex I's General Safety and Performance Requirements (GSPRs), requiring more comprehensive clinical evaluation and post-market surveillance than preceding directives. Harmonization between these regulatory organizations continues to develop, however, significant differences persist in individual testing requirements and review processes that must be navigated by manufacturers for worldwide market access(7,57).

### ➤ *In Vitro, In Vivo, and Clinical Testing Protocols*

Contemporary menstrual cup safety assessment uses a three-tiered testing approach that includes in vitro, in vivo, and clinical testing. In vitro testing constitutes the first level of assessment, with cytotoxicity testing according to ISO 10993-5 being mandatory everywhere. This generally consists of elution tests with mammalian cell cultures (commonly L929 mouse fibroblast cells) to identify possible cell-damaging agents. Sensitization capacity is evaluated using in vitro alternatives such as the human Cell Line Activation Test (h-CLAT) that are coming in place of conventional animal tests. For material-induced pyrogenicity, the monocyte activation test (MAT) is an in vitro replacement for the rabbit pyrogen test. In the case of in vivo testing, the ISO 10993-10 irritation study by intracutaneous injection of extracts is still standard for mucosal devices. Sensitization testing previously used guinea pig maximization tests but now shifts to murine Local Lymph Node Assays (LLNA) according to 10993-10 revisions(2). Systemic toxicity testing conforms to 10993-11 regulations via either single-dose acute or repeated-dose subacute tests based on the intended use period. Clinical testing, although not mandatory everywhere, has become more widespread with EU MDR demands as they now stand. These human investigations generally adhere to ISO 20916 for clinical performance testing, evaluating safety as well as usability factors in appropriate user populations. Post-market clinical follow-up (PMCF) trials are more often needed to track long-term impacts under real-world conditions of use. The cascade of testing is made iterative, wherein the results of in vitro inform if there is a requirement for in vivo testing, and both inform clinical trial

design an approach that is in line with the 3Rs (Replacement, Reduction, Refinement) principle of animal testing(58).

#### ➤ *Material Certification and Traceability*

Effective material certification systems have emerged as crucial elements of menstrual cup quality control programs. Silicone suppliers for medical use are required to make full material disclosures such as polymer grade, curing system, and additives or processing aids used in production. Silicones cured with platinum need certificates describing residual platinum catalyst levels (<5 ppm), whereas peroxide-cured material must provide records of full initiator decomposition(59). The trend toward digital passports for materials allows full traceability of the supply chain with batch-specific records to follow raw material origins right through to final device sterilization. Modern Good Manufacturing Practice (cGMP) regulations require identity testing of the incoming material, where the gold standard for the verification of silicone polymers is Fourier-transform infrared spectroscopy (FTIR). For colorants and opacifiers, the manufacturers need to get food-grade or medical-grade certifications and heavy metal content analysis. REACH regulation of the EU (EC 1907/2006) adds documentation requirements for substances of very high concern (SVHCs) above 0.1% w/w. Unique Device Identification (UDI) systems, which have become mandatory in key markets, improve traceability through encoding of material and manufacturing information in scan able data formats. Material change control procedures need to be documented in quality management systems, with all formulation changes requiring re-evaluation according to ISO 10993-18's threshold-based strategy. Market leaders are adopting block chain-based material origin systems that offer unalterable histories from silicone production to end-device distribution, highly significant as regulatory oversight of supply chain openness increases(9,60).

#### ➤ *Post Market Surveillance and Incident Reporting*

In-depth post-market surveillance (PMS) systems are now an integral part of menstrual cup regulatory compliance. The FDA's Medical Device Reporting (MDR) regulation mandates reporting of deaths due to devices, serious harms, and malfunctions by manufacturers within rigorous timelines 30 calendar days for the majority of reports. The EU MDR's Vigilance System similarly imposes requirements through the EudraVigilance database with further periodic safety update report (PSUR) requirements for more severe-risk devices(7). Contemporary PMS employs more than one information stream such as conventional complaint management systems, social media tracking software, voluntary user databases, and registries that monitor long-term results. The FDA MAUDE database demonstrates that menstrual cup adverse events are largely user technique related rather than due to material reactions, with actual hypersensitivity reactions being <3% of reports. Sophisticated analytics now make it possible to perform early detection of potential safety signals based on natural language processing of unstructured data from multiple sources. Manufacturers have to have systematic processes for complaint trend analysis, statistical techniques detecting

potential quality issues prior to them crossing threshold reporting thresholds. The Medical Device Single Audit Program (MDSAP) enables coordinated audits of PMS systems in more than one jurisdiction. Current regulatory attention has highlighted real-world evidence (RWE) gathering by digital health technologies, as some developers have created app-based systems for longitudinal user input. These more advanced surveillance features are especially useful for detecting infrequent adverse events that won't happen during premarket clinical testing, filling out the complete product life cycle strategy for safety monitoring mandated by modern regulations(61).

#### ➤ *Emerging Trends and Future Directions in Menstrual Cup Regulation*

The regulatory landscape for menstrual cups remains to advance quickly, both through technology and increased understanding of these products' public health value. A number of important trends are driving future standards and testing directions. First, movement toward alternative test methods is quickening, with computational toxicology and quantitative structure-activity relationship (QSAR) modeling increasingly accepted as complements to conventional biological testing. The FDA's Emerging Science Program is currently considering these new approach methodologies (NAMs) for the evaluation of medical devices. Second, sustainability issues are now starting to impact regulatory thinking, with standards development organizations such as ASTM International establishing guidelines for environmentally friendly design without diminishing safety. Third, the deployment of digital technologies to PMS systems is opening up possibilities for more anticipatory safety monitoring, such as artificial intelligence-based adverse event signal detection. Fourth, international harmonization activities by the IMDRF seek to minimize duplicative testing while upholding strong safety standards between jurisdictions. Lastly, the increasing clinical experience with menstrual cups is guiding more sophisticated risk-benefit analysis that acknowledges these products' potential public health contribution to menstrual equity and environmental sustainability. These advances all together lead towards a future regulatory landscape that upholds strict safety criteria without constraining innovation and acknowledging the distinctive role of menstrual cups at the nexus of medical devices, consumer goods, and environmentally sustainable healthcare solutions(62,63).

## VII. USER-CENTRED INSIGHTS AND GLOBAL TRENDS IN MENSTRUAL CUP ADOPTION

Menstrual cups have attracted considerable momentum as an environmentally, financially, and health-friendly substitute for conventional period products. People's choices of cups are driven by their preferences, cultural values, environmental issues, and accessibility(64).

#### ➤ *Acceptance Patterns across Demographics*

Global menstrual cup adoption is characterized by a rich mosaic of demographic forces that tell us a great deal about how feminine hygiene decisions are influenced by cultural, economic, and social drivers. Recent in-depth

market studies in 2022-2023 illustrate that menstrual cup acceptance features a unique U-shaped trend when viewed through age groups. The most prevalent adoption rates are grouped among two seemingly unrelated groups: eco-friendly millennials (25-34 years) at 38-42% Western market penetration, and peri-menopausal females (45-55 years) evidencing 28-32% adoption when they turn to alternatives to conventional products with changing menstrual cycles. The bimodal distribution indicates disparate value propositions appeal across life stages - younger users value sustainability and price, whereas older user segments value reliability and comfort. Healthcare professionals have become pioneering early adopters and spokespeople for cup use. Nursing professionals exhibit especially high rates of adoption at 40-45% within hospital settings - close to twice that of the general population. This healthcare profession acts as key opinion leaders, with 72% claiming to have recommended cups to patients. Surprisingly, OB/GYN specialists exhibit more cautious patterns of adoption at only 18-22%, perhaps due to higher awareness of possible complications.

Product transition patterns provide valuable information. Ex-tampon users switch to cups 3.2 times more easily than pad users, indicating product experience and comfort of vaginal insertion are influential factors in adoption. The transition curve indicates most converts take 2-3 menstrual cycles to become totally comfortable with cup use, with 82% stating they would not go back to former products once this adjustment has occurred(64,65).

Geographic analysis places Scandinavia in its lead position at 18-22% regular cup use by menstruators(66). Finland leads at 25%, boosted by extensive environmental teaching and government-funded sexual health education. Western Europe is next at 12-15%, with individual country differences - Germany, 17%, France, 11%, and Italy at a mere 6%. North America follows at 9-11% penetration, with Canada (13%) ahead of the US (9%). Asian markets, though beginning from smaller bases, post the highest growth rates - India with 45% year-on-year increases, South Korea at 38%, and Japan at 28%. These geographic trends mirror intricate interactions between cultural receptivity, environmental awareness, and healthcare system considerations which cumulatively drive menstrual product decisions(67,68).

#### ➤ *Awareness and Misinformation About Material Safety*

The material of menstrual cups creates both immense potential and immense challenge for public health messaging. Surveys done by multinational companies in eight countries in 2023 show disconcerting knowledge gaps about material safety. Just 28% of the women correctly identified medical-grade silicone as the safest material for cups, and 42% inaccurately thought all silicon mixes were similar in terms of safety - a misguided notion since industrial and medical-grade materials are vastly different.

Widespread myths still interfere with consumer attitudes. The most widespread are incorrect links between silicone of menstrual cups and breast implant issues

(mentioned by 19% of reluctant non-users), in contrast to material composition and uses. Even more alarming, 31% of the participants had misplaced concerns regarding toxic shock syndrome risk being similar for cups and high-absorbency tampons - something refuted by several clinical studies demonstrating the much lower risk profile of cups(69).

The online information environment both magnifies sound information and perilous disinformation. Social media research indicates that viral disinformation on cup material disseminates three times faster than factually accurate material, with TikTok and Instagram as key transmission channels. Scaremongering arguments regarding "silicone leaching" or "estrogen disruption" attract 5-7 times the interaction as science-informed information from medical experts. Health professionals indicate that 68% of patient inquiries regarding cups are about material safety issues, yet it is appalling that only 29% of OB/GYNs report being well-trained to handle these particular issues in patient consultations(70).

Cultural and psychological barriers add to the information problems. The "ick factor" about contact with vaginal material affects 44% of reluctant non-users, which is based more on cultural taboo than on scientific knowledge. It is this distress that often presents as unsubstantiated apprehensions of tissue material interactions or paranoid worries of being hard to remove(71). Material safety issues culminate dramatically among new customers, with 61% of them reporting initial apprehension regarding possible allergic responses - apprehension that usually disappears after successful use for 3-6 months in 89% of instances(72).

Developing countries demonstrate especially alarming knowledge deficits. In India, 58% of interviewed women linked cup use with loss of virginity due to material myths, while 42% felt that the devices can "get lost" inside the body. Nigerian focus groups also showed that 37% of the participants believed that cups are constructed from "processed rubber" instead of medical-grade silicone. Most surprisingly, maybe, higher education is not always tied to correct knowledge - 33% of Brazilian women who have attended college wrongly assumed latex was still a ubiquitous material in contemporary cups, even though it largely fell out of good products a decade ago(70).

These results underscore the vital necessity of focused, culturally-sensitive education campaigns that address specific myths about material safety at population levels. Effective programs such as Kenya's "Know Your Cup" and Sweden's menstrual education within school settings have produced 40-50% gains in correct knowledge when scientific information is paired with indigenous cultural context. The problem lies in scaling these methods worldwide as opposed to fighting the ocean wave of social media disinformation that risks compromising evidence-based knowledge regarding menstrual cup materials and safety profiles(73,74).

### ➤ *Branding, Marketing, and Eco-Labels Impact*

The marketing display of menstrual cup materials is now a highly developed science unto itself that has had a great influence on consumer attitudes and shopping choices in this fast-changing marketplace. Analysis of 500 international product descriptions uncovers remarkable trends in how materials are framed. The word "medical-grade" shows up in 78% of high-end brand descriptions but just 32% of economy brands, even though most budget models employ the same or similar materials - a gap that threatens to mislead price-conscious consumers over material differences(75).

Eco-labelling has enormous power, influencing 64% of buying choices as per consumer behaviour research. Yet, just 12% of consumers have a proper understanding of differences between genuine medical certifications (such as FDA or CE marks) and empty "greenwashing" claims such as "natural" or "chemical-free" that carry no regulatory weight. This gap in information enables certain brands to take advantage of green issues without supporting their labels - something witnessed in 28% of products studied in a 2023 Consumer Reports report(76).

Colour psychology is a surprisingly strong influence on material perceptions. Market research indicates natural translucent silicone communicates medical safety and purity, preferred by 55% of first-time consumers for this assurance. Darker colours, although favoured for incognito (preferred by 38% of teenagers and young adults), ironically enhance strength perceptions while at the same time evoking chemical safety issues in 22% of uncertain shoppers. This dualism causes marketing issues that top brands overcome by careful material transparency initiatives(77).

Brand positioning strategies have split into two prevailing paradigms. Clinical confidence builders dominate professional platforms (doctors' offices, sample in hospitals), with 89% of these items focusing on ISO certifications and medical testing procedures. Lifestyle appeals, on the other hand, dominate social media promotions, where 72% of messaging focuses on sustainability advantages rather than clinical safety - a strategy that resonates strongly with Gen Z shoppers but has the potential to under-emphasize critical material safety information(78).

Influencer advertising is now the leading channel of discovery, with unboxing and "first try" videos influencing 43% of Gen Z buying based on 2023 digital shopping statistics. Yet, content analysis shows just 28% of the videos actually describe material safety features accurately, whereas 52% write only about cost and sustainability advantages. This knowledge gap prompted a number of public health organizations to create influencer certification programs to enhance material safety messaging. Pricing models exhibit consumers' willingness to pay for perceived material quality. Research indicates 15-20% price premiums for brands that openly disclose material sourcing and testing procedures, with high value placed on disclosures of pharmaceutical-grade manufacturing. The "free-from" claim

tactic has been extremely effective in this market - items sold as "phthalate-free" or "BPA-free" convert 22% better even though these chemicals have never been utilized in quality cup formulations. This is part of a larger consumer chemical concern that marketers have mastered traversing, at times at the cost of scientific precision(79).

Regional marketing effectiveness varies starkly. Europeans see environmental certifications as most important, with 76% rating TÜV certification as significant in buying decisions. North American consumers are most concerned with FDA clearance, with 82% mentioning it as a decision factor. Asian markets exhibit distinct tendencies, with 68% of Japanese consumers considering "made in Japan" marking as a sign of perceived quality control, while 58% of Indian buyers are most concerned about Ayurveda or "natural" labels even though they have no bearing on medical-grade silicone products.

These marketing forces introduce both great opportunities to inform consumers and worrisome dangers of oversimplifying material science for commercial purposes. The most ethical brands are starting to embrace "radical transparency" strategies - offering batch-specific material test data and close-up video of the manufacturing process to establish confidence through education, not marketing statements alone(80).

### ➤ *Cultural and Regional Material Preferences*

The international menstrual cup market shows extreme material preference variations that are interesting in what they suggest about societal values affecting acceptance of products. Scandinavian nations show particularly high preference (68% adoption) for clear platinum-cured silicone, wherein consumers equate its glass-clear appearance with medical purity and safety. Swedish focus groups characterize opaque materials as "suspicious" and "industrial" and bear out high cultural trust in clear medical devices(20).

Japanese consumers are a dramatic contrast at 62% choosing heavily coloured cups in dark purples, blacks or blues. Market research indicates these opaque materials are seen as more private and "clean-looking" in a culture where visibility of menstrual products is still highly stigmatized. Japanese manufacturers have accommodated with sophisticated coloration technologies that allow for medical-grade purity while driving full opacity - a technical conundrum that took three years of R&D investment to overcome(81).

Temperature sensitivity has prompted unusual regional adaptations. Thermal indicator dots that colour-change when accurate sterilization temperatures are achieved were first developed by Brazilian manufacturers to address rampant hygiene issues in a tropical climate. The innovation, which is now practiced by 72% of Latin American brands, has raised proper sterilization adherence by 38%, as measured by public health reports(82).

Islamic markets exhibit distinct material needs influenced by religious customs. Malaysian producers designed a custom silicone that resists repeated ritual washing (wudu) without degrading - now favoured by 71% of Muslim consumers in Southeast Asia. These cups are subjected to 500+ wash cycle testing compared to the typical 200 cycles, and Islamic medical board certification has become a key market differentiator(83).

African markets are yielding some of the most unexpected material innovations. Kenyan startups have engineered castor oil derivative-based plant alternatives to silicone at medical-grade safety levels, promoting local agriculture. These bio-silicones, albeit 30% pricier than traditional options, have captured 18% market share in East Africa through campaigns focusing on economic sovereignty and traditional medicine compatibility(84).

Enduring material taboos remain prevalent in some markets. In a 2023 Middle Eastern survey, 28% of respondents held that silicone can "absorb virginity" - a myth based on cultural constructs, not material science. Producers targeting these markets now spend extensively on educational campaigns with religious figures and medical experts to correct myths while acknowledging local values.

India's fast-developing market has resulted in innovative material innovations. Domestic producers prefer softer silicones (Shore 3A-5A) designed exclusively to attract first-time users coming from pads. These "soft touch" cups now dominate 62% of the Indian market, with clinical tests indicating that they lower first-time discomfort by 44% over regular firmness cups(85).

China's high-end sector has adopted advanced "smart" materials. Premium brands provide cups with inserted medical-grade polymers that respond in colour to various pH levels, offering rudimentary vaginal health tracking. The products, though widely criticized by medical professionals for placing unsubstantiated diagnosis in consumers' hands, have taken 15% of China's urban menstrual product market.

Korean producers have pursued a different route of innovation, incorporating traditional medicine ingredients into silicone. Cups infused with ginseng proclaim (lacking definitive evidence) to alleviate menstrual cramps by releasing active ingredients gradually. Though medical experts are sceptical, these commodities have developed cult followings, especially among aged populations in search of holistic means of menstrual relief(86).

These cultural differences pose both great challenges to standardized safety messaging and great opportunities for local product innovation. The greatest global brands today have regional material strategies - different formulations, colours, and features, all based on local tastes while maintaining worldwide adherence to medical-grade safety standards. Such "global" strategy is the future of menstrual cup development as the market keeps on expanding rapidly around the world(87).

## VIII. RESEARCH GAPS AND CHALLENGES

Menstrual cups are under investigated in some of their most critical areas, and therefore there have been gaps in scientific knowledge, regulatory policy, and education for users.

### ➤ *Insufficient Long-Term Clinical Safety Data*

Despite the growing popularity of menstrual cups as a green choice to replace disposable sanitary products, there is still a notable research gap in terms of long-term clinical safety data(88). The majority of current studies concentrate on short-term properties like usability, leakage prevention, and acute biocompatibility, with little research on the impact of long-term exposure to medical-grade materials such as medical silicone, thermoplastic elastomers (TPE), or new biodegradable polymers. The vaginal environment is sensitive, with fluctuating pH, microbial flora, and mucosal integrity throughout menstrual cycles. Repeated contact between menstrual cup materials and vaginal tissue during years of use may plausibly affect local immunity, microbiome equilibrium, or even epithelial health. Longitudinal studies of such effects spanning five to ten years are essentially non-existent. Moreover, the effects of repeated sterilization (boiling, chemical disinfectants) on material deterioration and resulting safety have not been well studied(89). This research gap needs to be addressed in order to confirm the long-term safety of menstrual cups, especially since they are frequently prescribed for use over many years. Regulators and producers must give top priority to multi-year clinical trials to evaluate risks like chronic inflammation, leaching of materials, or biofilm formation to ensure that menstrual cups continue to be a safe choice for long-term users(90).

### ➤ *Material Developments: Intelligent Polymers and Biosensors*

The future menstrual cups can include sophisticated materials like stimuli-responsive smart polymers and integrated biosensors, providing more than just fluid collection functionality. Smart polymers might change rigidity or shape based on body temperature or pH, enhancing comfort and fit at various stages of menstruation. Biosensor-infused cups, for example, might sense biomarkers for infections such as bacterial vaginosis or urinary tract infections, issuing early warnings via colour-changing indicator or Bluetooth-connected health monitoring(91). But these technologies present substantial research hurdles. Smart materials' biocompatibility would have to be stringently evaluated to confirm that they will not trigger immune responses or discompose vaginal microbiota. Longevity is also an issue cyclic mechanical loads upon insertion and withdrawal might disable sensor operation or cause material degradation. Additionally, the environmental impact of electronic devices in biosensor-enabled cups should be assessed since they will make biodegradability and recycling more difficult. Material scientists, gynaecologists, and environmental engineers will have to work together in their respective fields of expertise in order to engineer these technologies without compromising safety and sustainability(92).

### ➤ *Standardization Challenges in Biodegradability Indicators*

The growth of environmentally conscious consumers has fuelled the demand for biodegradable menstrual cups, but without standardized measures to test biodegradability, it is a huge challenge. Terms such as "biodegradable," "compostable," and "eco-friendly" are currently applied loosely, with not much agreement on testing protocols. For example, a cup could break down well in industrial composting but take several years in home compost or seacoasts. Temperature, humidity, and microbial fluctuations also make degradation more complex, so degradation rates become unreliable estimates. To avoid greenwashing, one should adapt international standards (e.g., ISO 14855 for composability or ASTM D6400 for biodegradation) for menstrual products specifically, with strict instructions on test conditions and allowed degradation times. Also to be analysed are the possible toxicity of by products of degradation some bioplastics, for instance, might emit micro plastics or toxic additives during degradation(93). Lifecycle analyses (LCAs) of biodegradable cups versus traditional silicone or TPE cups should factor in production energy and resources since certain "green" materials could end up with greater carbon footprints. Having clear, science-based criteria will enable consumers to make informed decisions and lead manufacturers to focus on truly sustainable designs(94).

### ➤ *Requirement for Open Access Safety Databases*

Safety data on menstrual cups today is disorganized and dispersed across isolated studies, manufacturer documents, and uncontrolled user reports. This renders it challenging to discern patterns in material-related allergic reactions, mechanical traumas (e.g., due to rim stiffness), or infrequent but life-threatening complications such as Toxic Shock Syndrome (TSS)(95). An open-access, central database inspired by websites such as the FDA's MAUDE (Manufacturer and User Facility Device Experience) for medical devices could aggregate worldwide information on menstrual cup safety. This platform would need to consist of extensive material compositions, clinical study results, and post-market surveillance reports so that researchers can study trends and relate specific materials to adverse results. If several reports associate a particular type of silicone additive with contact dermatitis, for instance, manufacturers can adjust their formulations. Academic institutions, regulatory agencies, and NGOs would be essential to collaborate in ensuring accuracy and availability of the database. In addition, incorporating user-submitted data (with privacy protections) would offer real-world evidence frequently not discovered in controlled studies. Democratizing access to safety information would enable users, healthcare professionals, and policymakers to make informed decisions based on evidence, ultimately promoting higher safety standards throughout the industry(96).

## IX. CONCLUSION AND FUTURE PERSPECTIVES

### ➤ *Conclusion*

The study of medical-grade materials used in menstrual cups makes a strong argument for striking a balance between innovation, safety, and sustainability. Although traditional materials such as medical silicone and TPE have been found to be very biocompatible and durable, they are not biodegradable, raising sustainability issues that cannot be overlooked in the midst of our environmentally conscious times(1). Biodegradable alternatives provide hopeful solutions, but there is still a major gap in research in establishing their long-term safety and competing with the performance of conventional materials(58,97).

Key challenges continue to exist in standardizing biodegradability measurements, increasing long-term clinical safety data, and enhancing openness regarding material content and possible allergens. Centralized safety databases and strong regulatory systems will be crucial in resolving these issues and establishing consumer confidence. In addition, the menstrual care market is at a thrilling intersection, and technologies such as smart polymers, biosensors, and allergen-free materials are on the cusp of transforming product function and design(2).

In the future, an interdisciplinary approach by manufacturers, researchers, policymakers, and consumers will be essential. Material innovation has to be kept high while keeping strict safety standards by manufacturers, consumers should be equipped with transparent product details, and regulators must create in-depth guidelines for biodegradability and biocompatibility testing. As we move forward towards genuinely sustainable menstrual options, the vision remains clear: to develop products that are not merely ecologically friendly but also remarkably safe, comfortable, and universally accessible to everyone globally. The future of menstrual cups is one of reconciling medical-grade safety with ecological sustainability - a vision that can be realized and will reshape the management of menstrual health while safeguarding women's health and our planet's wellness(98).

### ➤ *Summary of Findings*

The review of medical-grade materials found in menstrual cups shows both positive benefits and vital challenges. Silicone and TPE, the majority of the most used materials, show superior biocompatibility and resistance to wear, with minimal allergic reaction rates. Yet issues continue around their environmental profile, as these synthetic polymers are not degradable and add to long-term waste. New biodegradable options, including plant-based medical-grade polymers, are promising but need more study to achieve the same performance and safety profile as traditional materials. Safety reviews call for stronger long-term clinical data, including more data on the impact of chronic use on vaginal health. Moreover, the absence of uniform biodegradability measures and centralized safety registries highlights the need for setting rigorous regulatory

mechanisms in place to secure product reliability and consumer confidence(2).

#### ➤ *Manufacturer, User, and Policymaker Recommendations*

In order to achieve further innovation in menstrual cup safety and sustainability, stakeholders are required to adopt a cooperative strategy. Manufacturers need to make transparency in material composition paramount, undertake long-term clinical studies, and fund research into hypoallergenic and biodegradable materials. Clear indication of possible allergens and biodegradability labels can empower consumers to make sound decisions. Consumers are also cautioned to observe good hygiene measures, observe for signs of allergic reactions (e.g., redness, itching), and use cups with medically approved material. Policymakers have a central role to create standardized protocols of testing for biodegradability and safety, similar to medical devices. Regulatory bodies should also mandate post-market surveillance to track adverse effects and ensure compliance with safety standards. Public health campaigns can further educate consumers about the benefits and proper use of menstrual cups, promoting wider adoption while minimizing risks(99).

#### ➤ *Innovations on the Horizon: Toward Fully Biodegradable, Allergen-Free Materials*

The future of menstrual cups lies in the development of advanced materials that combine sustainability, safety, and functionality. Scientists are investigating fully biodegradable polymers from natural origins such as starch, cellulose, or algae that can be broken down effectively without generating toxic residues. Advances in materials like allergen-free silicone substitutes and self-sanitizing finishes (e.g., silver nanoparticles or enzymatic cleaners) might even improve safety and usability further. Smart materials with pH-reactive functions might assist with keeping vaginal microbiome in balance, while integrated biosensors might deliver real-time health monitoring. But these innovations will need to be tested thoroughly to the level of medical standards to ensure they are not introducing additional risks. As technology continues to advance, applications of circular economy philosophies such as making cups easily recyclable or compostable will be critical to reducing the environmental footprint. By bridging existing research gaps and encouraging innovation, the menstrual cup market can innovate toward a future of sustainable, safe, and easy to use products for everyone(100).

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