Summary:

A new quantitative method for determining patient risk for reusable medical device categorization based on using and interpreting Kremer's cleaning classification system

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Background & Rationale

For decades, the Spaulding classification has been the global standard for categorizing reusable medical devices according to their contact with patients. This framework defines devices as critical, semi-critical, or non-critical, guiding the level of reprocessing required (sterilization, high-level disinfection, or low-level disinfection). While robust and widely adopted, Spaulding's model presumes that devices are thoroughly cleaned prior to disinfection or sterilization. In reality, cleaning is often the most variable and failure-prone step in reprocessing, particularly for devices with increasingly complex designs such as narrow lumens, sharp internal corners, or multi-material interfaces. [1,2]

Residual contamination on such features can compromise sterilization efficacy and pose infection risks to patients. Furthermore, device innovation trends toward miniaturization, multifunctionality, and advanced materials have outpaced current reprocessing guidance. Experts increasingly recognize that "cleanability" - the inherent ability of a device to be effectively cleaned - must be explicitly factored into risk assessments, yet current frameworks fail to address this dimension. [1,2]

Objective

This study introduces and validates the Kremer Cleaning Classification System (KCCS) - a structured, quantitative, and risk-based methodology designed to assess the cleanability of reusable medical devices. The system aims to complement and extend Spaulding's classification by incorporating a cleanability layer, providing healthcare facilities, manufacturers, and regulators with a more holistic approach to patient risk management.

Methods

Device Feature Testing

A total of 23 distinct device features were experimentally assessed under challenging cleaning conditions to determine which geometries and design attributes present the highest cleaning difficulty. Key focus areas included:

Fluid dynamics: How cleaning solutions flow through and interact with device channels.

Soil retention: The likelihood of organic matter adhering in recesses, lumens, and junctions.

Risk Scoring & Classification System

A structured scoring matrix was developed, integrating 14 targeted questions addressing geometry, material properties, surface finish, device use environment, and cleaning variability. Each device (or device feature) is assigned a numerical risk score, with the most difficult-to-clean feature setting the baseline.

Risk categories were defined as:

- Minimal Risk: Score < 18
- Moderate Risk: Score between 18 and 39
- Maximal Risk: Score ≥ 40

Conceptual Integration

The KCCS was mapped against ISO 14971 principles of risk management and designed to align with the emerging ISO/TS 17664-3 draft, which seeks to harmonize validation frameworks for reusable medical device cleaning instructions.[2]

Key Findings

Categorization by Cleanability: The KCCS successfully stratified devices into distinct cleanability-based risk groups, providing objective differentiation where Spaulding alone falls short.

Time-to-Dry Factor: Soil drying time emerged as a critical determinant of cleaning efficacy; once soil residues dried, removal was significantly more difficult regardless of device design.

Transparency through Scoring: Numerical scoring improved objectivity, repeatability, and clarity, reducing reliance on subjective judgment in cleaning validation.

Feature-Based Testing: Complementary research demonstrated that testing specific high-risk features (e.g., blind lumens) is more accurate than whole-device assessments, which can mask localized failures. This method proved rigorous across 56,000 cleaning cycles, minimizing the risk of "false pass" results where an instrument looks clean overall but still has dirt hidden in hard-to-reach spots.[3]

Implications

Patient Safety: By assessing cleanability into classification enables tailored reprocessing strategies, reducing the likelihood of infection transmission due to reprocessing failures.

Design-for-Cleanability: Manufacturers receive actionable feedback during product development, fostering device designs that are easier to clean and maintain.

Regulatory & standards impact: The system may inform future revisions to ISO validation standards (TS 17664-3) and industry best practices, promoting harmonized, risk-informed cleaning validation worldwide.[1]

Operational Efficiency: Risk classification enables healthcare providers to customize reprocessing workflows, allocate resources effectively, and monitor critical loads more precisely.

Sustainability benefits: Data-driven cleanability analysis supports optimized reuse, enhancing environmental sustainability without compromising safety.[1]

Conclusion

The Kremer Cleaning Classification System represents a significant advancement beyond the traditional Spaulding framework by explicitly incorporating cleanability into patient risk assessment for reusable medical devices. Through a structured, quantitative scoring approach, it provides greater objectivity, transparency, and alignment with evolving international standards. By enabling tailored reprocessing strategies, informing device design, and supporting regulatory harmonization, the KCCS offers a robust and future-oriented tool for enhancing patient safety, operational efficiency, and sustainability in medical device reprocessing.

Summary Table

Dimension	Key Takeaways
Existing Limitation	Spaulding ignores cleanability aspect - a key gap with modern complex devices
New Contribution	Kremer system quantitatively assesses cleanability through device features
Methodology	23 features tested; 14-question risk scoring; three risk tiers (<18, 18–39, ≥40)
Additional Validation	Feature-based validation is more conservative than whole-device testing
Benefits	Improved safety, design feedback, regulatory alignment, and sustainability
Future Integration	Potential inclusion in ISO standards; facilitates data-driven cleaning strategies

References

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