QSIA™

Structural Analysis for Complex Systems

Structural Analysis

Ethicon / J&J Medical Devices

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Methodology	Structural Analysis for Complex Systems (QSIA™)
Framework	QuantoMathics™

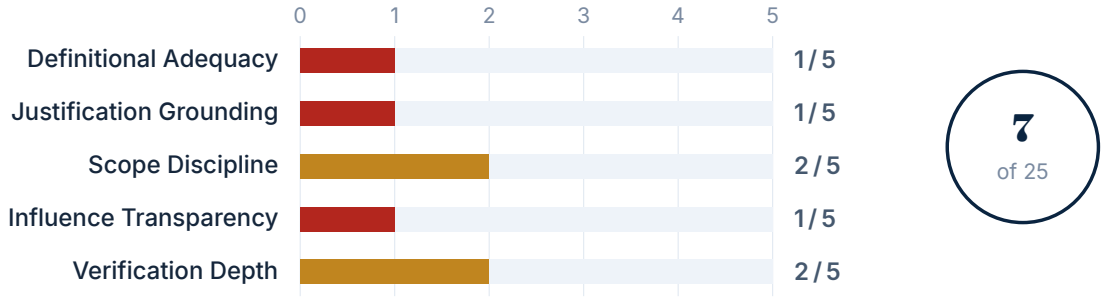
Contents

1 Executive Summary

This report applies the Structural Analysis (QSIA) methodology to Johnson & Johnson's Medical Devices segment (Ethicon, DePuy Synthes), examining whether the organization's declared product-quality architecture sustains structural integrity under operational load.

The analysis identifies concurrent structural failures across four product categories (transvaginal mesh, hernia mesh, hip replacement, surgical staplers) and two divisions (Ethicon, DePuy Synthes) over a 21-year period (2005 to 2026), alongside genuine organizational adaptation at the portfolio level.

Diagnostic Condition	Score
Definitional Adequacy	1 / 5
Justification Grounding	1 / 5
Scope Discipline	2 / 5
Influence Transparency	1 / 5
Verification Depth	2 / 5
Composite	**7 / 25**



Condition scores (0 to 5), colored by severity, with the composite profile.

The organization's deepest structural property is that its governance architecture adapts at the portfolio level (restructuring, spin-offs, rebranding) while the product-quality architecture persists unchanged. The root structural failure is scope: the quality architecture was built for surgical sutures and remained unbuilt for the expanded product portfolio that acquisitions introduced. Every downstream failure, definitional erosion, interface gaps, verification blindness, traces to this scope breach. Financial scale absorbs the consequences ($4.4 billion in settlements for a single product line), dampening the correction signal before it reaches the structural root.

A composite score of 7/25 for an organization generating roughly $30 billion in annual medical device revenue[1] reflects a structural profile in which the governance shell is functional but the product-quality core is persistently compromised. The organization continues to operate. It absorbs.

Revision note. Version 2.0 (May 2026) revises the original six-condition analysis (March

2026) to align with the current five-condition QSIA framework. Old Condition 5 (scalability / verification density) absorbed into Influence Transparency. Old Condition 6 (organizational adequacy) becomes Verification Depth. Scope-to-interface layering committed: Scope Discipline is the structural root; Influence Transparency failures are its operational manifestation. No evidence altered.

2 About the Methodology

2.1 Structural Analysis for Complex Systems

The Structural Analysis (QSIA) evaluates whether a complex system can sustain operation without destabilizing itself, scale without structural degradation, preserve definitional adequacy under stress, and maintain verification pathways. The methodology is domain-invariant: the same diagnostic framework applied here is applied to governance architectures, software systems, financial models, and organizational decision pipelines.

The analysis target in this engagement is the **product-quality architecture as instantiated in actual J&J Medical Devices operations**: not the corporate governance documents in isolation, and not the full competitive or regulatory environment. The declared quality specifications are examined as design claims; the operational history (FDA records, litigation, settlements, recalls) is examined as the system those claims produced. Where the two diverge, both are within scope, because the distance between them is itself a structural diagnostic.

2.2 Methodological Scope

The QSIA diagnoses *absolute* structural properties: whether a system satisfies the conditions required for sustained coherent operation. It does not produce *relative* rankings between organizations. An organization that scores low on Definitional Adequacy does so because its declared product specifications diverge from actual device performance, not because some other manufacturer maintains them better.

Some structural properties identified in this analysis (regulatory bypass, known-flaw deployment, signal suppression) may be present in other medical device manufacturers or other industries. The QSIA framework would diagnose those properties as structural vulnerabilities wherever they appear. The absence of comparative ranking is deliberate: the purpose is to identify what is structurally vulnerable in *this* organization, not to claim it is uniquely vulnerable.

2.3 The Five Diagnostic Conditions

The QSIA evaluates five structural conditions:

1. **Definitional Adequacy.** The system's declared product identities must maintain stable correspondence with actual device performance. When a product's declared safety profile diverges from its clinical reality, definitional adequacy has failed.
2. **Justification Grounding.** Safety-critical parameters must be validated before products enter broad clinical deployment. Products deployed on unvalidated or known-to-be-inadequate foundations violate this condition.
3. **Scope Discipline.** The organization's product portfolio must remain within the scope its quality architecture can govern. Expansion into new product categories without corresponding quality-architecture expansion breaches the scope boundary. This condition is foundational: when scope is breached, interface failures (Condition 4) follow as the operational manifestation.
4. **Influence Transparency.** The organization's declared quality architecture must corre-

spond to its actual operational quality. Cross-component interfaces must maintain direct mutual verification: signals must cross divisional and functional boundaries with binding effect. This condition encompasses both the declared-vs-actual gap and the verification pathway integrity (cross-component signal transfer, detection-to-correction binding, cross-division quality learning).

5. **Verification Depth.** Under organizational change (restructuring, growth, transition), structural conditions must be preserved or repaired. An organization whose governance adapts while its product-quality conditions persist unchanged exhibits only partial resilience under change.

2.4 Analysis Protocol

The QSIA operates in three phases:

- **Phase 1: Structural Mapping.** Construction of the organization's operational map: component inventory (divisions, product lines, regulatory interfaces, quality systems), dependency classification, identification of declared vs. actual quality architecture, and critical-path analysis.
- **Phase 2: Feedback Integrity Analysis.** Feedback loop detection, foundational parameter analysis, hidden coupling identification. All findings are stated conditionally: where specified structural conditions hold, a defined vulnerability class follows.
- **Phase 3: Verification Depth Assessment.** Governance transition analysis, structural preservation testing under change scenarios, stress simulation. Evaluates whether the system's dynamic operations preserve or degrade the conditions assessed in Phases 1 to 2.

Each QSIA finding admits an inspectable reasoning chain that traces back to observable structural facts.

2.5 Scope and Limitations

This analysis treats J&J Medical Devices as a product-quality architecture: a structural system subject to the same integrity conditions as any complex system that claims to maintain coherent operation under scaling. It does not evaluate individual clinical outcomes, assign legal liability, or assess financial health. It is a structural diagnostic, not a legal or financial opinion. It is independent of, and not affiliated with, authorized by, or endorsed by Johnson & Johnson, and it offers no investment advice.

All evidence cited is from public-domain sources: FDA enforcement records, federal and state litigation filings, judicial decisions up to the U.S. Supreme Court, publicly disclosed settlement amounts, and corporate restructuring announcements through March 2026.

3 Structural Map of the Architecture

3.1 Component Inventory

Component Type	Instances	Classification	Structural Function
Divisions	Ethicon, DePuy Synthes	Operational	Primary product-authority nodes
Product families	Sutures, mesh, staplers, hip/knee, spine	Product	Revenue and risk units
Regulatory interfaces	FDA, Health Canada, EU MDR	Verification	External compliance gates
Quality systems	Design controls, post-market surveillance	Internal verification	Declared checking layer
Corporate governance	Board, MedTech leadership, BU heads	Authority	Decision and adaptation architecture
Litigation interface	MDL courts, state AGs, settlements	External correction	Forced accountability

Table 1. Component inventory of the J&J Medical Devices architecture.

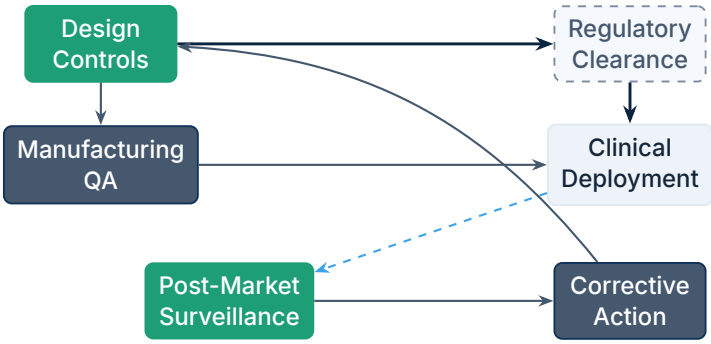
3.2 Dependency Classification

Dependency Type	Examples	Structural Function
Regulatory authorization	FDA clearance, PMA, 510(k)	Market entry gate
Quality verification	Design controls, clinical trials	Internal safety validation
Post-market surveillance	Adverse event reporting, recalls	Operational monitoring
Cross-division coordination	Quality signal transfer, shared learning	Portfolio-level integrity
Corporate oversight	Board review, compliance audits	Governance adaptation
External enforcement	Litigation, state AG actions, FDA orders	Forced correction

Table 2. Dependency classification in the declared quality architecture.

3.3 Declared Quality Architecture

J&J's declared quality architecture follows the standard medical device governance model:



Declared quality architecture: the closed correction loop as specified. Design controls validate, regulatory clearance confirms, deployment proceeds, post-market surveillance detects deviations, and corrective action closes the loop.

Node classes:

Decision Model Metric Data Control Verification External

Edge types:

- Authorization
- Metric influence
- Data feedback
- Control signal
- Incentive
- Informational

The declared flow: design controls validate safety → regulatory clearance confirms validation → manufacturing quality assurance maintains specification → post-market surveillance detects deviations → corrective action closes the loop.

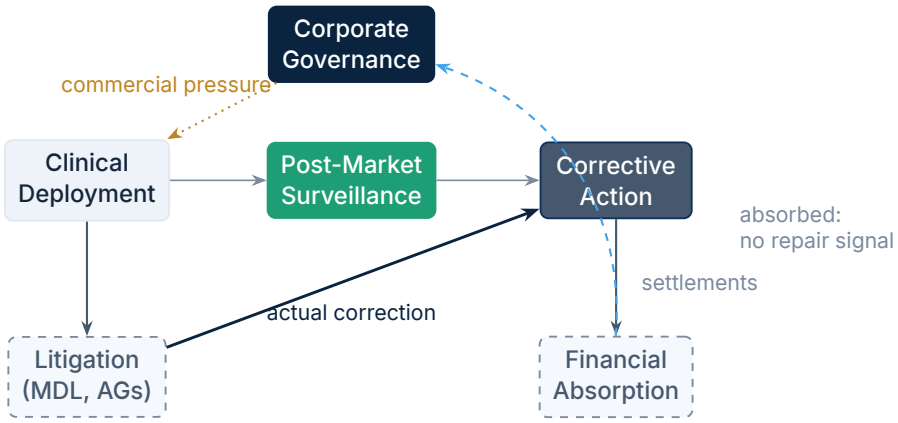
3.4 Undocumented Dependencies: The Gap Between Design and Operation

The following components are operationally consequential but do not appear in the declared quality architecture:

- **Commercial pressure on regulatory timeline.** The pace at which products are pushed to market is driven by competitive and revenue targets, not by the quality architecture's readiness assessment. Prolift's market entry without standard FDA review is the clearest evidence that commercial pressure overrode the declared regulatory gate.
- **Litigation as the actual correction mechanism.** The declared architecture specifies post-market surveillance and voluntary corrective action as the feedback loop. The operational reality is that litigation forced product withdrawals in every major failure case. The actual correction mechanism is external and adversarial.
- **Financial absorption capacity.** J&J's ability to absorb $4.4 billion in settlements while continuing to operate is a financial-scale feature, separate from the quality architecture. The consequence: structural failure at the product level is financially absorbed before

it produces the organizational consequences (destabilization, forced transformation) that would normally compel structural repair.

- **Divisional silos.** Ethicon and DePuy Synthes operated as independent divisions with separate quality cultures. The same failure pattern appearing independently in both divisions indicates that the cross-divisional quality-learning interface was either absent or inoperative.
- **Regulatory delegation.** FDA increasingly delegates certification to manufacturers. This is not part of J&J's declared quality architecture, but it fundamentally alters the structural meaning of "FDA-cleared": the regulatory gate that the quality architecture depends on for external validation has been partially internalized to the manufacturer.

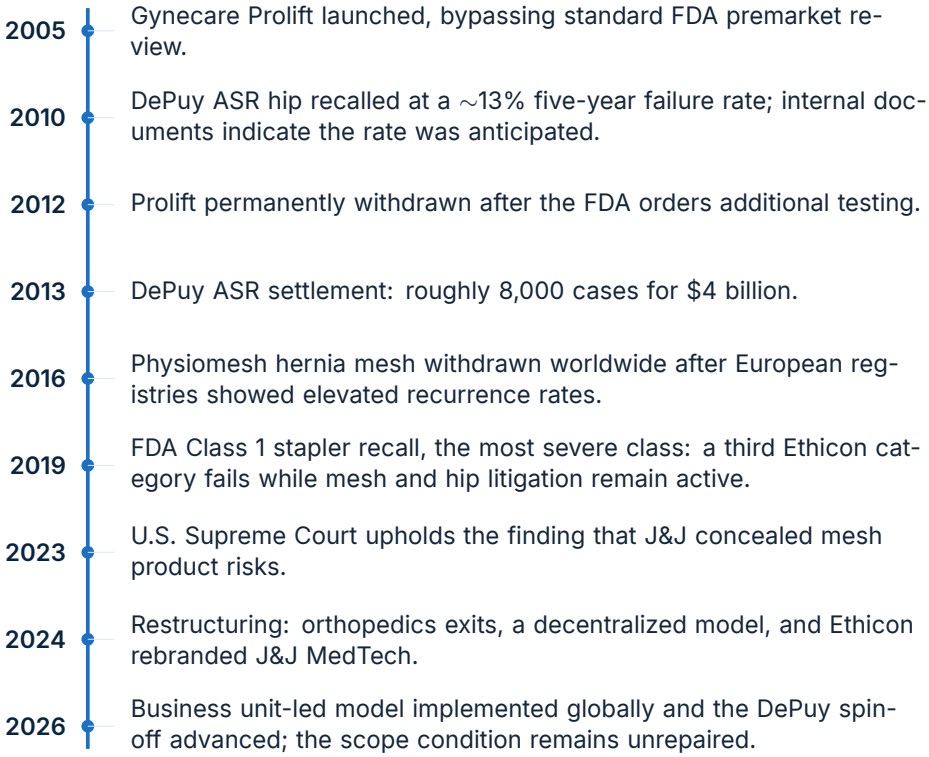


Actual governing dependencies. The declared loop (faint) is present but not load-bearing: correction is forced externally by litigation, while financial absorption dampens the signal before it reaches governance and compels structural repair.

These are not incidental omissions. They define the distance between what the quality architecture declares and how product quality actually operates. When the organization evaluates itself against its declared quality design, these forces are invisible, rendering structural self-assessment systematically blind to the dynamics that produce recurring failures.

4 Evidentiary Record

This section presents the public-domain evidence organized by product category. No analytical interpretation is applied here; the structural analysis follows in Section 5.



Two decades of recurring structural failure across four product categories, alongside governance adaptation that leaves the scope condition unrepaired.

4.1 Transvaginal Mesh: Gynecare Prolift (2005 to 2023)

- **2005 to 2008:** Gynecare Prolift introduced to the US market without separate FDA premarket review; the device was not formally cleared by the FDA until 2008, and more than 100 adverse-event reports were filed with the FDA in the interim.[2]
- **2007 to 2012:** Adverse events accumulate. Product remains on market.
- **June 2012:** FDA orders post-market surveillance studies; Ethicon withdraws four transvaginal mesh products, including Prolift, from the market.[3]
- **October 2019:** Multistate settlement of $117 million with 41 states and the District of Columbia over deceptive marketing of pelvic mesh, with no admission of liability.[4]
- **2019:** $120 million single-plaintiff jury verdict (Susan McFarland, Philadelphia), among the largest individual Ethicon pelvic-mesh awards.[5]
- **February 2023:** The U.S. Supreme Court declined to review the case, leaving intact a $302 million California judgment that Ethicon deceptively marketed pelvic mesh by minimizing its risks.[6]

Market exposure after first recall: 5 years. **Total timeline:** 18 years (2005 to 2023).

4.2 Hernia Mesh: Physiomesh and PROCEED (2010 to 2026)

- **2010 to 2016:** Physiomesh Flexible Composite Mesh in active clinical use.
- **2006, 2011, 2014:** Multiple recalls of Ethicon PROCEED surgical mesh for incomplete package seals and delamination that could compromise sterility.[7]
- **May 2016:** Ethicon issues a voluntary worldwide market withdrawal of Physiomesh Flexible Composite Mesh after two European hernia registries showed higher recurrence and revision rates than comparator meshes.[8]
- **Settlements (amounts undisclosed):** Ethicon resolved Physiomesh claims through confidential settlements. As of 2026 the Physiomesh MDL has been resolved, with 224 plaintiffs settled and no cases remaining pending.[9]

Active litigation span: 10 years (2016 to 2026).

4.3 DePuy ASR Hip Replacement (pre-2010 to 2026)

- **August 2010:** ASR XL Acetabular hip system recalled worldwide (roughly 93,000 implants); a UK joint registry showed an approximately 12 to 13% five-year failure rate.[10]
- **Internal data:** A 2011 internal J&J review projected a revision rate near 37% within 4.6 years (about 40% within five years), and documents disclosed at trial indicate executives were aware of the design flaw before the 2010 recall.[11]
- **Complications:** Component loosening, fracture, dislocation, metal sensitivity, elevated metal ions, necrosis, tissue damage.
- **November 2013:** Settlement of nearly 8,000 ASR cases for $4 billion.[12]
- **March 2015:** An additional 1,800 cases settled for $420 million, bringing total ASR settlements above $4.4 billion.[13]
- **March 2026:** 119 cases remain pending in MDL 2197 (Ohio).

Total ASR settlements: $4.4 billion. **Separate litigation:** DePuy Pinnacle hip (independent MDL).

4.4 Surgical Staplers (2019 to 2025)

- **2019:** FDA Class 1 recall (the most severe class) of Ethicon circular staplers, approximately 92,500 devices; seven serious injuries and one death reported to Ethicon.[14]
- **April to July 2025:** Ethicon issued a correction letter in April 2025 regarding lockout failures in Endopath Echelon vascular stapler reloads; the FDA classified the issue as a Class 1 recall in July 2025, affecting nearly 700,000 units.[15]

Structural significance: Third Ethicon product category exhibiting the failure pattern, emerging while mesh and hip litigation still active.

4.5 Stable Product Line: Sutures and Wound Closure

Ethicon's original product line has maintained quality standards since the 1940s, achieving a dominant share of the global suture market (historical estimates place Ethicon's postwar worldwide share around 70%, and its US share around 80%)[16] with no major quality failures or regulatory actions in the public record. This structural control demonstrates the organization can sustain product integrity in its core historical domain.

4.6 Organizational Restructuring (2023 to 2026)

- **2023:** J&J consolidates its medical-device divisions (Ethicon, DePuy Synthes, and others) under the Johnson & Johnson MedTech brand; "Ethicon" is retained as a product brand within the segment.[17]
- **2023 to 2025:** Substantial portfolio and workforce realignment within MedTech, including market and product-line exits and a shift toward a decentralized, business-unit-led operating model.[18]
- **October 2025:** DePuy Synthes orthopedics spin-off announced as a standalone company (target 18 to 24 months; roughly $9.2 billion in FY2024 orthopedics sales).[19]

Three major restructurings in three years. Active governance adaptation.

4.7 Aggregate Financial Exposure

Category	Public Amount	Status
Transvaginal mesh (multistate)	$117 million	Resolved
Transvaginal mesh (largest verdict)	$120 million	Resolved
Hernia mesh (Physiomesh)	Confidential	224 settled; 0 pending
DePuy ASR hip	$4.4 billion	119 pending
MedTech restructuring	Not publicly disclosed	Ongoing
Surgical staplers	Not quantified	Ongoing
Industry-wide mesh (all mfrs)	$1+ billion (est.)	~38,000 suits resolved

Table 3. Aggregate public financial exposure. Confirmed J&J settlements exceed $4.4 billion.

5 Condition 1: Definitional Adequacy

Definitional adequacy requires that every product's declared identity (its safety specification, its regulatory status, its clinical indication) maintains a stable, verifiable correspondence with actual device performance. When the declared identity persists but the reality it refers to degrades or was never established, definitional adequacy has failed.

5.1 The Pattern: Four Product Categories, One Failure Mode

Every major product failure in the J&J Medical Devices portfolio exhibits the same definitional structure: a product carries a declared safety identity ("FDA-cleared surgical mesh," "safe hip replacement system," "approved hernia repair device") whose actual clinical performance does not sustain what the identity declares.

> Finding: Definitional adequacy has failed across four product categories in two divisions over 21 years. The failure is systemic, not episodic.

5.2 Case Studies in Definitional Erosion

5.2.1 Transvaginal Mesh: Identity Without Validation

Gynecare Prolift entered the market carrying the identity "FDA-cleared surgical mesh for pelvic organ prolapse repair." That identity implied clinical validation through standard regulatory review. The product bypassed premarket approval. The declared identity was applied to a device whose actual safety profile had not been established through the pathway the identity implied.

The gap was present from market entry and widened over seven years. The Supreme Court ultimately upheld that risks were concealed. This is not a case of identity degradation over time; it is identity misapplication from the start.

5.2.2 Hernia Mesh: Specification Failure at Population Scale

Physiomesh carried the identity "approved hernia repair device." Clinical data showed higher than expected recurrence and complication rates. The declared quality specification did not match actual device performance across the patient population. Same definitional failure mode as the transvaginal mesh, appearing independently in a second product category.

5.2.3 ASR Hip: Known Identity-Reality Gap

The DePuy ASR hip carried the identity "safe hip replacement system." Internal documents suggest the company predicted catastrophic failure rates and that executives were aware of design concerns. The 13% five-year failure rate at recall confirmed the gap. This is not merely definitional erosion; it is identity maintenance in the presence of known specification failure: the gap was known internally and sustained externally.

5.2.4 Surgical Staplers: Pattern Recurrence

The Class 1 stapler recall extends the definitional failure to a third Ethicon product category, emerging six years after the mesh withdrawals. Safety designations applied to devices whose performance did not sustain them: the same structural dynamic, recurring independently.

5.3 The Integrity Paradox: Core vs. Expanded Portfolio

The suture and wound closure line demonstrates that the organization can maintain definitional adequacy in its core historical product domain (70% worldwide market share, no major failures). The definitional failures concentrate in products involving newer technologies, expanded scope, and acquisitions.

> Paradox: The same organization maintains product integrity in mature, well-understood product categories while failing repeatedly in expanded categories. Definitional adequacy is domain-correlated, not organization-wide. The quality architecture sustains what it was originally built for and fails when extended beyond that scope.

6 Condition 2: Justification Grounding

This condition assesses whether safety-critical parameters are validated before products enter broad clinical deployment. In the medical device context: was the product's safety established (genuinely, not just formally) before it was implanted in patients at scale?

6.1 Regulatory Bypass: Foundation Never Established

> Finding (Critical): Gynecare Prolift entered broad clinical deployment without completing standard FDA premarket review. The foundational safety parameter was never established.

The declared quality architecture specifies regulatory clearance as the foundational gate: design controls validate safety, regulatory review confirms validation, then deployment proceeds. Prolift bypassed this gate. The product entered broad clinical use (implantation across multiple sites in multiple patients) without the foundational parameter (validated safety profile) having been closed.

This is the most direct form of closure failure: the closure mechanism was circumvented entirely.

6.2 Formal Closure Without Substantive Closure

> Finding: The DePuy ASR hip completed a regulatory process, but internal evidence suggests the company possessed data contradicting the safety conclusion. The regulatory formality was completed; the engineering reality was not.

This is a structurally distinct failure mode. The foundational gate was not bypassed: it was satisfied formally while being violated substantively. The regulatory process produced a "cleared" status that the company's own internal data indicated was incorrect.

A system whose foundational verification can be satisfied formally while being violated substantively has a verification architecture whose ground is the paperwork itself. The formal process checks paperwork; the correspondence between paperwork and reality goes unverified.

6.3 The Two Failure Modes

The Ethicon/DePuy evidence reveals two independent mechanisms by which justification grounding fails in the medical device context:

1. **Bypass:** The closure process is circumvented entirely (Prolift). The product enters deployment without passing through the declared safety gate.
2. **Formal-without-substantive closure:** The process completes but internal evidence contradicts the conclusion (ASR hip). The product enters deployment carrying a "validated" status that the manufacturer knows to be unreliable.

Both produce the same structural outcome: broad scaling on an unvalidated foundation.

Both undermine the quality architecture's foundational premise: that products reaching market have been validated as safe.

> Structural Observation: The quality architecture assumes that regulatory clearance constitutes foundational closure. When that assumption fails (through bypass or through formal-without-substantive completion), every downstream quality process operates on an unvalidated base. Post-market surveillance, adverse event reporting, and corrective action all presuppose that the product was validated before deployment. When it was not, the entire downstream architecture is structurally compromised.

7 Condition 3: Scope Discipline

Scope discipline requires that the organization's product portfolio remains within the boundaries its quality architecture can govern. When the portfolio expands beyond what the quality systems were designed to manage, the scope boundary has been breached. This condition is foundational in the J&J analysis: the scope breach is the structural root from which downstream interface failures (Condition 4) follow as operational manifestations.

7.1 The Original Scope

Ethicon's quality architecture was originally built for a single product domain: surgical sutures and wound closure. This is a mature, well-characterized product category with decades of manufacturing experience, established clinical evidence, and stable regulatory requirements. The quality architecture sustains this scope.

7.2 The Scope Breach

Between 2005 and 2019, Ethicon and J&J Medical Devices expanded into product categories with fundamentally different risk profiles:

- **Implantable mesh products** (transvaginal, hernia): Long-term implant with complex tissue interaction, population-scale variability in outcomes, and regulatory pathways that were less established than for sutures.
- **Metal-on-metal orthopedic devices** (ASR hip): High-consequence implant with failure modes (metal ion release, tissue necrosis) not present in the suture domain.
- **Complex surgical instruments** (staplers): Mechanical devices used in real-time surgical settings with failure modes (misfiring, lockout) that produce immediate patient harm.
- **Acquired product lines** (Mentor, Acclarent, NeuWave, Megadyne, TachoSil): Each acquisition brought new product categories, new manufacturing processes, and new quality cultures that needed integration.

These are not extensions of the suture domain. They are new product categories whose risk profiles require their own verification criteria. The quality architecture's scope boundary was not correspondingly expanded. Products with novel failure modes were governed by verification systems designed for a different product domain.

> Finding: The product portfolio expanded across multiple high-risk categories while the quality architecture was not rebuilt for the new scope. The organization added new product domains without expanding its quality closure.

7.3 Acquisition-Driven Scope Growth

Between 2009 and 2019, Ethicon made five significant acquisitions: Mentor (2009), Acclarent (2010), NeuWave (2016), Megadyne (2017), and TachoSil (2019). Each acquisition expanded the product portfolio and introduced new quality-system integration requirements.

Acquisition is the fastest mechanism for scope expansion and the most structurally dangerous: the acquiring organization inherits a product portfolio without inheriting the institutional knowledge, quality culture, and manufacturing discipline that produced it. The quality architecture must absorb new product categories, new failure modes, and new regulatory requirements simultaneously.

The temporal correlation is notable: the period of most aggressive acquisition (2009 to 2019) overlaps with the period of most active product failures and litigation.

7.4 The Scope-Interface Layering

> Structural Observation: The scope breach is the enabling condition for the interface failures diagnosed in Condition 4. Once the quality architecture governs products outside its original closure, every interface between the architecture and a non-suture product exhibits verification failure. Scope failures and interface failures are not competing diagnoses; they operate at different structural levels. Scope (Condition 3) is the root. Interface (Condition 4) is the operational manifestation. This layering matters for repair: addressing interface gaps without rebuilding the quality architecture for the actual scope repairs symptoms while leaving the structural cause operative.

8 Condition 4: Influence Transparency

This condition examines whether the organization's declared quality architecture corresponds to its actual operational quality, whether verification signals cross component boundaries with binding effect, and whether cross-division quality learning is operative. As established in Condition 3, the interface failures diagnosed here are structurally downstream of the scope breach: once the quality architecture governs products outside its original closure, interface verification failures are the operational manifestation of that deeper scope violation.

8.1 The Declared Structure vs. the Actual Structure

Declared quality architecture:

- Design controls validate product safety before market entry
- Regulatory clearance confirms validation through independent review
- Manufacturing quality assurance maintains specification in production
- Post-market surveillance detects deviations in clinical use
- Corrective action closes the feedback loop

> Finding (Critical): The actual quality system bears limited structural resemblance to the declared architecture. The distance between the two is the largest single interface vulnerability.

Actual quality system (per operational evidence):

- **Regulatory bypass:** Prolift entered the market without completing the declared regulatory gate. The declared architecture's foundational interface was circumvented.
- **Known-flaw deployment:** The ASR hip was deployed despite internal evidence of design inadequacy. The declared architecture's design-control interface was overridden by commercial pressure.
- **Delayed corrective action:** Prolift remained on market for five years after the first recall. The declared architecture's corrective-action loop operated on a timescale that allowed continued patient harm.
- **Litigation as correction:** In every major failure case, external pressure (FDA orders, litigation volume, Health Canada recall) forced product withdrawal. The actual correction mechanism is adversarial and external.
- **Signal suppression:** In the ASR case, the internal detection system generated the signal (predictive data on failure rates), but the organizational pathway from detection to corrective action was blocked. The declared post-market surveillance loop existed on paper; the organizational reality suppressed its output.

8.2 The Regulatory Delegation Problem

FDA increasingly delegates device certification to manufacturers through the 510(k) pathway and other mechanisms. When the regulatory interface relies on manufacturer self-certification, the interface between "regulatory clearance" and "validated safety" depends entirely on the manufacturer's internal integrity.

The Prolift case demonstrates the consequence: when a manufacturer exploits a less rigorous regulatory pathway, the external validation gate that the quality architecture depends on becomes structurally inoperative. The regulatory interface did not fail because the FDA failed; it failed because the interface was designed to rely on manufacturer integrity, and that integrity was not present.

> Finding: The regulatory delegation pattern creates a structural vulnerability in every medical device manufacturer, not only J&J. But the J&J evidence demonstrates the consequence with particular clarity: when the external validation interface is weakened, the entire quality architecture's foundational assumption (that regulatory clearance means validated safety) is undermined.

8.3 The Signal-to-Action Gap

> Finding (Critical): In the DePuy ASR case, internal verification generated the signal: predictive data indicating catastrophic failure rates. The organizational pathway from signal to corrective action was blocked. The verification system worked; the organization did not act.

This is the most diagnostically significant interface failure. The question is not whether the organization can detect problems (it can, at least in some cases). The question is whether the pathway from detection to action is structurally intact. In the ASR case, it was not. The signal was generated; the response was suppressed.

A verification architecture whose outputs can be organizationally suppressed functions as a monitoring system only, with the binding connection to the correction mechanism severed.

8.4 Cross-Division Learning Failure

The temporal sequence is the strongest evidence of interface failure at the portfolio level:

- Transvaginal mesh failures: 2005 to 2012
- ASR hip recall: 2010
- Hernia mesh failures: 2010 to 2016
- Surgical stapler recall: 2019
- Stapler correction: 2025

Each new failure emerged despite the organization having experienced and resolved prior failures. The structural question is whether the detection architecture could prevent the next

failure. The evidence shows that each failure emerged independently, detection arriving only under external pressure, the architecture learning from one incident only within the division where it occurred.

> Finding: Quality lessons remained siloed within each division and each product category. The 21-year record shows the same failure pattern recurring across units that operated in isolation from each other. This is the interface mechanism by which the pattern persists.

8.5 The Evaluation Problem

The organization evaluates its quality performance against its declared quality architecture, not against its actual operational quality. When J&J assesses whether its quality systems are functioning, it evaluates against the declared design (design controls, post-market surveillance, corrective action). The actual dynamics (commercial pressure overriding regulatory gates, signal suppression, litigation-forced correction) are invisible to declared-structure evaluation.

This explains a persistent feature of J&J's quality history: the quality architecture can be "functioning" (all declared processes operating) while products are simultaneously failing in the field. The declared design and the actual system have different integrity conditions.

9 Condition 5: Verification Depth

Verification Depth tests whether structural conditions (Conditions 1 to 4) are preserved or repaired under organizational change: leadership transition, restructuring, growth, and external pressure. A system satisfies this condition when its dynamic operations do not degrade the conditions that were assessed as holding (or do not prevent repair of conditions that were assessed as failing).

9.1 Genuine Governance Adaptation

The 2023 to 2026 restructuring demonstrates genuine dynamic capability at the governance level: orthopedics exit ($700 to 800M), decentralized BU model (35,000 employees), DePuy spin-off, globally implemented BU-led model. Three major restructurings in three years is active governance adaptation under pressure. The organization navigates transitions without losing operational continuity.

9.2 Structural Conditions Not Repaired Through Transitions

The 21-year pattern of Condition 1 failures raises a structural question about whether that resilience holds completely. Governance adapted at the portfolio level (restructuring, spin-offs, rebranding) while the Condition 3 scope boundary remained unrepaired, and its Condition 1/Condition 4 consequences persisted through those transitions. The same failure patterns recur in new product categories and new divisions despite repeated organizational change.

The DePuy spin-off may acknowledge that multi-division structure created silos blocking cross-divisional quality interfaces. Separating DePuy simplifies governance while leaving the scope-boundary breach and the failure pattern appearing independently in both divisions structurally intact. Governance-level reorganization operates above the level where product-level failures originate.

> Finding: Resilience under change exists at the governance level: the organization can restructure, divest, and reorganize. At the structural-condition level, the Condition 3 scope boundary and its Condition 1/Condition 4 consequences persist through every transition. The organization's dynamic operations preserve its survival while its structural integrity remains unaddressed.

10 Verification Architecture Analysis

The QSIA assesses the organization's verification channels at four structural levels.

10.1 Level 1: Internal Consistency Checks

Internal consistency verification exists within each division: design control reviews, manufacturing quality audits, documentation compliance checks. These mechanisms verify that a division's outputs satisfy its own procedural requirements. They are generally functional for established product lines (sutures). They failed to prevent the introduction of products with unvalidated safety profiles (Prolift) or known design flaws (ASR hip).

10.2 Level 2: Cross-Component Verification

Cross-division quality signal transfer is the organization's Level 2 mechanism: quality lessons from one product line or division should inform risk assessment in others. This is the declared architecture's weakest point.

> Finding: The public record is silent on effective cross-division quality learning. The mesh failures preceded the stapler failures; the DePuy failures preceded continued Ethicon patterns. Each division's quality lessons remained internal to that division. Level 2 verification is absent or inoperative.

10.3 Level 3: System-Level Integrity Analysis

Level 3 requires examination of whether the quality architecture as a whole is achieving its structural purpose: preventing the introduction and continued sale of products whose actual performance diverges from their declared safety profile.

The public record is silent on system-level structural self-examination. Corporate quality reviews and compliance audits assess whether declared processes are followed; whether those processes are sufficient remains outside the audit scope. The quality architecture checks its own procedures while its own effectiveness goes unexamined.

> Verification Finding: Level 3 verification is absent. The quality system checks whether its processes are followed; whether those processes prevent the failures they are designed to prevent lies outside its reach. This is the quality-architecture equivalent of a financial audit that checks arithmetic while the business model goes unexamined.

10.4 Level 4: External Verification

Level 4 would require verification from outside the organization entirely. The regulatory interface (FDA, Health Canada) partially fills this role but has been structurally weakened by delegation.

The actual Level 4 mechanism is litigation: external, adversarial, and independent of the organization's quality claims. In every major failure case, litigation forced the accountability response. This is an emergent verification mechanism, operating after harm has occurred.

> Finding: The organization's external verification architecture has been reduced to litigation. Regulatory verification has been partially internalized through delegation. The quality architecture's actual external check is adversarial, reactive, and activates only after patients have been harmed.

11 Deep Structural Diagnosis

11.1 Original vs. Emergent Fragility

Original architectural vulnerabilities:

1. Quality architecture built for a single product domain (sutures) with no formal mechanism for extending to novel risk categories (Condition 3 original limitation)
2. Dependence on regulatory clearance as the foundational safety gate, without independent internal verification of the gate's substantive validity (Condition 2 design assumption)
3. No formal cross-division quality-learning mechanism (Condition 4 architectural absence)
4. Governance architecture designed for a suture manufacturer, not a multi-domain conglomerate (Condition 5 original scope)

Emergent structural failures:

1. Definitional erosion across four product categories in two divisions over 21 years (Condition 1 escalation)
2. Regulatory bypass (Prolift) and formal-without-substantive closure (ASR hip) exploiting the foundational assumption (Condition 2 deepening)
3. Scope-boundary breach through portfolio expansion and five acquisitions (Condition 3 dissolution)
4. Declared quality architecture disconnected from actual quality operation; signal-to-action pathways blocked; cross-division interfaces absent (Condition 4 escalation, downstream of Condition 3)
5. Governance restructures without repairing the Condition 3 scope boundary or its Condition 1/Condition 4 consequences (Condition 5 degradation)

The original vulnerabilities are **enabling conditions** for the emergent failures, with the Condition 3 scope boundary as the structural root. The single-domain architecture enabled scope-boundary breach. The breach then generated the Condition 1 failures and Condition 4 verification gaps that constitute its operational manifestation. The Condition 2 dependence on regulatory clearance enabled bypass. The governance architecture's inability to reach the Condition 3 level through restructuring enabled the pattern to persist.

11.2 The Reinforcing Degradation Cycle

1. Scope-boundary breach (Condition 3) $\rightarrow$ introduces novel risk categories outside the quality architecture's original scope. This is the root structural failure.
2. Scope breach generates definitional failures (Condition 1) $\rightarrow$ new products carry declared identities the quality architecture cannot validate, because the architecture was not built for those risk categories.
3. Definitional failures manifest as interface gaps (Condition 4) $\rightarrow$ every interface between

the quality architecture and a non-suture product exhibits the downstream expression of the scope breach. Signal-to-action pathways severed, cross-division interfaces absent, litigation becomes the only operative correction.

4. Dynamic operations stay above the structural root (Condition 5) → governance restructures at the portfolio level while the Condition 3 scope boundary and its consequences persist unchanged at the product level.
5. Financial absorption dampens the correction signal → the organization absorbs $4.4B, so the feedback that should force scope repair (rebuilding the quality architecture for the actual portfolio) dissipates before reaching the structural level.

This is a **structurally reinforcing degradation cycle** with the scope breach as its root. The cycle's stability derives from insulation: every available correction pathway is structurally insulated from the Condition 3 level where failures originate. Interface repairs address symptoms while the scope breach remains operative. Governance restructuring operates above the scope level. Litigation addresses financial consequences while the scope-boundary violation persists. This insulation is what makes the pattern stable rather than transitional.

11.3 The Fundamental Structural Limitation

> Core Structural Diagnosis: J&J Medical Devices operates a quality architecture whose Condition 3 scope boundary was breached by portfolio expansion and remains unrepaired. The Condition 5 governance layer adapts (restructuring, spin-offs, rebranding) while the scope breach and its Condition 1/Condition 4 consequences persist unchanged. Financial scale absorbs the downstream manifestations, dampening the correction signal before it reaches the Condition 3 level where the structural root lies. The organization survives its own quality failures. Its architecture reproduces them.

The system's correction mechanisms are all either internal (quality processes that the organization controls and can override), formally external but substantively weakened (regulatory delegation), or adversarial and reactive (litigation). An architecturally independent verification layer, one that operates before harm occurs and whose outputs carry binding force, is absent.

A system whose only effective correction mechanism is litigation after patient harm is structurally limited to **financial accountability**. It can be made to pay for failures. Prevention lies outside what its architecture can deliver.

12 Fragility Scorecard

12.1 Scoring Scale

Each condition is evaluated against predefined sufficiency predicates: operationally checkable conditions independent of the diagnostic conclusion. The scoring scale is fixed across all QSIA engagements:

Score	Meaning
0	**Structurally absent.** The condition requirement is not met at any level.
1	**Materially deficient, no durability.** The enforcing mechanism is present but does not bind, or carries no margin, under operational load.
2	**Materially deficient, partial.** The mechanism binds partially, or carries thin margin, insufficient to sustain integrity under load.
3	**Minimally sufficient.** The condition requirement is met at a level adequate for current operation, though without significant margin.
4	**Strong.** The condition requirement is met with margin; the system tolerates moderate perturbation without degradation on this condition.
5	**Robust.** The condition requirement is met comprehensively; the system tolerates significant perturbation without degradation on this condition.

Table 4. QSIA Scoring Scale (fixed, domain-invariant).

External-evidence reading. For a structure assessed on external or public-record evidence, where exhaustive coverage cannot be observed, scores 4 and 5 are read as the defining stresses met with margin (5: the defining existential stresses met with margin), not as proof against every perturbation.

12.2 Summary Scorecard

Diagnostic Condition	Score	Basis
Definitional Adequacy	1 / 5	Four product categories, two divisions, 21 years of recurring definitional failure. Suture line stable but expanded portfolio systematically fails.
Justification Grounding	1 / 5	Regulatory bypass (Prolift). Formal-without-substantive closure (ASR hip). Foundational safety gate porous across multiple product lines.
Scope Discipline	2 / 5	Quality architecture built for sutures, extended to mesh, hip, staplers without proportional expansion. Core product scope maintained; expanded scope uncontained. Structural root of downstream failures.
Influence Transparency	1 / 5	Declared quality architecture diverges substantially from actual quality operation. Litigation is the actual correction mechanism. Signal suppression documented. No cross-division quality learning. 21-year pattern recurrence. Downstream manifestation of scope breach.
Verification Depth	2 / 5	Active restructuring demonstrates governance capability. Three restructurings in three years. Quality-level repair not yet demonstrated. Governance adapts; scope boundary not repaired.
Composite	**7 / 25**	

Table 5. QSIA Fragility Scorecard: J&J Medical Devices.

Note on interpretation. The composite score measures *structural integrity*: whether the quality architecture's own mechanisms are sufficient to sustain coherent operation, independent of business viability or organizational competence. A 7/25 means the quality architecture's structural integrity depends substantially on extra-architectural supports: financial absorption capacity, litigation-forced correction, and regulatory enforcement that compensate for gaps the quality architecture itself leaves open. The organization has survived $4.4 billion in settlements and continues to operate, but that resilience reflects financial scale, not quality-architecture soundness.

12.3 Scorecard Appendix: Predicates, Evidence, and Rationale

For each condition, this appendix documents (a) the sufficiency predicate, (b) the observed evidence, and (c) the scoring rationale.

Condition 1: Definitional Adequacy — Score: 1 / 5

Sufficiency predicate: Declared product identities (safety specification, regulatory status, clinical indication) maintain verifiable correspondence with actual device performance across the product portfolio.

Observed evidence:

- Four product categories exhibit identity-reality divergence: transvaginal mesh, hernia mesh, ASR hip, surgical staplers.
- Failures span two divisions (Ethicon, DePuy Synthes) and 21 years (2005 to 2026).
- The suture line maintains definitional adequacy, demonstrating the failure is domain-correlated.

Rationale: Scored 1 rather than 0 because the core suture product line does maintain definitional adequacy, demonstrating the organization possesses the capability. But the capability remains confined to the core domain while most product-level risk resides in the expanded portfolio.

Condition 2: Justification Grounding — Score: 1 / 5

Sufficiency predicate: Safety-critical parameters are validated (genuinely, not merely formally) before products enter broad clinical deployment.

Observed evidence:

- Gynecare Prolift bypassed standard FDA premarket review. Foundational safety parameter never established.
- DePuy ASR hip completed regulatory process while internal data contradicted the safety conclusion. Formal closure without substantive closure.
- Both mechanisms permitted deployment on unvalidated foundations.

Rationale: Scored 1 rather than 0 because the regulatory process does exist and does function for most products. The failures are in specific high-consequence cases where the foundational gate was either bypassed or substantively violated. The architecture is present; its enforcement is unreliable.

Condition 3: Scope Discipline — Score: 2 / 5

Sufficiency predicate: The product portfolio remains within the scope the quality architecture can govern. Expansion into new domains is accompanied by proportional quality-architecture expansion.

Observed evidence:

- Quality architecture built for sutures extended to mesh, hip replacement, and staplers.
- Five major acquisitions (2009 to 2019) expanded portfolio faster than quality architecture adapted.
- Core suture domain remains contained; expanded domains are not.

Rationale: Scored 2 rather than 1 because the organization does maintain scope containment in its original product domain and has demonstrated the ability to exit unprofitable markets (2023 restructuring). The scope mechanism exists but operates reactively (after failures) rather than proactively (preventing expansion beyond quality-architecture capacity).

Condition 4: Influence Transparency **Score: 1 / 5**

Sufficiency predicate: The declared quality architecture corresponds to actual operational quality. Verification signals cross component boundaries with binding effect. Cross-division quality transfer is operative.

Observed evidence:

- Regulatory bypass, known-flaw deployment, delayed corrective action, signal suppression, and litigation-as-correction define the actual quality system.
- Declared architecture diverges substantially from operational reality.
- No cross-division quality learning over 21 years. Mesh failures did not prevent stapler failures.
- Signal-to-action pathway blocked in ASR case (signal generated, response suppressed).
- Commercial pressure, financial absorption, and divisional silos are operationally dominant but architecturally invisible.

Rationale: Scored 1 rather than 0 because the declared quality channels do still function for routine operations and established product lines, and detection does eventually occur (adverse events are detected, recalls issued). But the interface is reactive, suppressible, and division-siloed, and its design reproduces the failure pattern.

Condition 5: Verification Depth **Score: 2 / 5**

Sufficiency predicate: Structural conditions (Conditions 1 to 4) are preserved or repaired through organizational change, transition, and restructuring.

Observed evidence:

- Three restructurings in three years (2023 to 2026). Active governance adaptation genuine.
- Condition 3 scope boundary not repaired through those transitions; same failure patterns recur in new divisions and product categories.
- Quality-level repair not yet demonstrated from public data.

Rationale: Scored 2 rather than 1 because the 2023 to 2026 restructuring demonstrates genuine organizational adaptation capability. The organization recognizes its governance architecture is inadequate and is actively reorganizing. This is more than most organizations demonstrate. But governance-level adaptation, absent scope-boundary repair, falls short of the sufficiency predicate. The question is whether dynamic capability at the governance level can be redirected to reach the Condition 3 level where failures originate.

13 Structural Remediation Pathways

This section identifies categories of structural change that would address diagnosed vulnerabilities. Organizational repair is a management question, not an engineering question, but the QSIA framework can identify the structural requirements any effective repair must satisfy.

Remediation pathways are organized by the QSIA tiered repair architecture:

- **Level 1 (Procedural):** Introduces formalized processes within the existing quality framework. Does not alter authority or control structures.
- **Level 2 (Institutional):** Adds structural roles that alter the quality architecture without redistributing organizational control.
- **Level 3 (Structural):** Modifies authority, control, or foundational quality structures. Strongest outcome, highest implementation difficulty.

13.1 Condition 1 Remediation: Definitional Adequacy

- **Level 1:** Mandatory pre-market identity-reality validation: before any product receives a declared safety identity, independent (non-commercial) verification that the actual device performance sustains the declared specification.
- **Level 2:** Standing product-identity review board with authority to challenge or revoke declared safety identities when post-market evidence diverges from the declared specification.
- **Level 3:** Structural separation between the commercial function (which benefits from maintaining product identity) and the quality function (which must be empowered to revoke it). This separation must be architecturally enforced, not merely declared.

13.2 Condition 2 Remediation: Justification Grounding

- **Level 1:** Formalized internal gate requiring substantive (not merely formal) safety validation before market entry. Documentation of the evidence base, not just the regulatory submission.
- **Level 2:** Independent internal review function (separate from the product-development team) with authority to block market entry when safety evidence is insufficient, regardless of commercial timeline.
- **Level 3:** Structural elimination of the bypass mechanism: no product reaches clinical deployment without passing through an independently verified safety gate whose outputs cannot be overridden by commercial pressure.

13.3 Condition 3 Remediation: Scope Discipline

- **Level 1:** Mandatory quality-architecture readiness assessment before entering new product categories or integrating acquisitions. No portfolio expansion without documented quality-system expansion.

- **Level 2:** Formal scope-containment threshold: if the quality architecture cannot demonstrate verified coverage of a new product category's risk profile, market entry is blocked until coverage is established.
- **Level 3:** Structural coupling between portfolio expansion decisions and quality-architecture capacity. Expansion authorization requires quality-function sign-off, not merely commercial approval.

13.4 Condition 4 Remediation: Influence Transparency

- **Level 1:** Mandatory disclosure of the actual quality-management structure (including commercial pressures, regulatory delegation reliance, and litigation history) in internal quality assessments. Formalized cross-division quality-signal sharing: every product-level event triggers cross-divisional review.
- **Level 2:** Independent quality-reality audit function evaluating the gap between declared and actual quality operations on a regular cycle. Centralized quality-intelligence function with cross-divisional authority for pattern recognition and preventive action.
- **Level 3:** Structural redesign of the correction mechanism: transition from litigation-as-correction (adversarial, reactive, post-harm) to internal correction with independent verification (proactive, pre-harm, architecturally embedded). Structural binding of verification signals to corrective action: if detection identifies a safety concern, the correction pathway activates without commercial approval.

13.5 Condition 5 Remediation: Verification Depth

- **Level 1:** Formal quality-condition assessment before each restructuring: does the proposed reorganization address the Condition 3 scope boundary or only governance structure?
- **Level 2:** Quality-architecture repair as explicit deliverable of every governance restructuring. Condition 1 to 4 condition improvement as measurable criterion for restructuring success.
- **Level 3:** Structural redesign ensuring dynamic operations (mergers, divestitures, reorganizations) include mandatory scope-boundary repair. Distinct quality systems per product domain with mandatory cross-domain interfaces and independent portfolio-level quality oversight.

13.6 The Missing Layer: Independent Product-Quality Verification

The most structurally significant repair would be the creation of an independent quality-verification function with authority and capacity to evaluate whether the product-quality architecture is achieving its stated purpose: preventing the introduction and continued sale of products whose actual performance diverges from their declared safety profile.

No such function currently operates effectively within J&J Medical Devices (per the public evidence). The regulatory interface has been weakened by delegation. Internal quality processes are subject to commercial override. The only independent verification mechanism with binding force is litigation, which operates after harm.

Whether such a function is organizationally feasible within a profit-driven medical device manufacturer is a management question. The structural observation is that the architecture lacks an independent quality-verification layer, and that absence is its deepest vulnerability.

14 Conclusion

Johnson & Johnson's Medical Devices segment is an organization of extraordinary scale and financial resilience. It generates approximately $30 billion in annual revenue, employs tens of thousands, and has absorbed $4.4 billion in settlements for a single product line while continuing to operate. It has restructured its governance architecture three times in three years, demonstrating genuine organizational adaptation capability.

The QSIA analysis reveals that the quality architecture's structural vulnerabilities are both original (a quality system built for sutures, dependence on regulatory clearance as the foundational gate, absent cross-division learning) and emergent (definitional erosion across four product categories, signal suppression, litigation as the actual correction mechanism), and that they interact to form a reinforcing degradation cycle with the scope breach as its root. The scope-boundary breach (Condition 3) introduces novel risk categories outside what the quality architecture was built to govern, generating definitional failures (Condition 1) that manifest as interface gaps (Condition 4). Dynamic operations (Condition 5) restructure governance while the Condition 3 level remains untouched, and financial scale absorbs the downstream consequences, dampening the correction signal before it reaches the structural root.

The organization's deepest structural property (the one that explains both its resilience and its persistent quality failures) is that its governance architecture adapts while the scope boundary and its consequences persist unchanged. Financial scale absorbs the consequences of quality failure. Litigation forces financial accountability after harm. Every correction mechanism operates after the fact; the architecture acts on failures it has already produced.

The 2023 to 2026 restructuring may represent a genuine inflection point. Whether it reaches the Condition 3 level, rebuilding the quality architecture for the actual portfolio scope, is the structural question whose answer will determine whether this organization's trajectory shifts from absorption to resolution.

The system continues to operate. Under the QSIA structural classification framework, a composite score of 7/25 with concurrent failures across multiple conditions and an absent self-correcting mechanism places this organization in the **Mixed Structural Profile** category: the governance shell functions, the product-quality core persists unchanged, and the distance between them is widening under portfolio expansion. The present pattern of recurring quality failures is structurally legible from the architecture: the failure tendencies the system exhibits are those its quality-architecture design makes increasingly likely under complexity load. That is the structural diagnosis.

Primary Source Index

Sources are numbered in order of first appearance in the text; the superscript number at each claim points to the corresponding entry below. The analysis draws on public-record sources only; figures carry the confidence levels noted after this list.

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[3]Drugwatch, "Transvaginal Mesh," device history and timeline. https://www.drugwatch.com/transvaginal-mesh/ (Ethicon voluntarily withdrew four mesh devices in June 2012; the FDA later banned surgical mesh for transvaginal POP repair in April 2019).

[4]Office of the New York State Attorney General, "Johnson & Johnson and Subsidiary to Pay $117 Million Settlement After Endangering Women's Health," October 2019. https://ag.ny.gov/press-release/2019/johnson-johnson-and-subsidi

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[17]MedTech Dive / FierceBiotech coverage of the Johnson & Johnson MedTech brand consolidation, 2023.

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[19]MedTech Dive, "J&J plans to spin out orthopedics business." https://www.medtechdive.com/news/jnj-spin-out-orthopedics/802696/

Data confidence notes

Figures are drawn from public-record sources. The points below record where precision is bounded or where a claim was corrected during verification; none is load-bearing for the structural diagnosis, which rests on the documented events above.

- **Suture market share.** The "~70% worldwide / ~80% US" figures are historical (postwar) estimates, not current shares; current analyses describe Ethicon as the leading suture maker without quoting a precise present-day percentage.
- **Settlement amounts.** Physiomesh settlement amounts are confidential; the public record supports 224 plaintiffs settled with no Physiomesh MDL cases pending and, across all mesh manufacturers, roughly 38,000 suits resolved with totals estimated above $1 billion. Per-plaintiff and Ethicon-only dollar figures are not public.
- **DePuy ASR pending count.** The "119 cases pending in MDL 2197" figure derives from the case file used to build this report and was not independently re-verified during this pass.
- **MedTech restructuring magnitude.** Specific internal figures (restructuring cost, headcount reorganized) are not publicly disclosed and are stated qualitatively rather than numerically.
- **Corrections applied during verification.** The brand consolidation under "Johnson & Johnson MedTech" is dated to 2023 (not September 2024); the Physiomesh event is a May 2016 worldwide market withdrawal (not a June 2016 Health Canada recall); the 2019 stapler recall covered ~92,500 units (not 100,000); and an unverifiable "April 2007 Prolift Class 2 recall" claim was removed.

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