



Case Study: Bringing the JFord Speculum Sleeve™ from Concept to FDA Clearance

The Core Problem or Opportunity

The JFord Speculum Sleeve™ was born from a clinical challenge that Dr. Jacqueline Ford had encountered repeatedly throughout her years in gynecologic practice. During routine pelvic examinations, standard vaginal speculums can be less effective in patients with larger body habitus, where redundant vaginal tissue may encroach into the examination field and limit clear visualization of the cervix.

While clinicians have developed workarounds over time, there was no dedicated, commercially available solution designed specifically to address this challenge using the speculums already found in most exam rooms. The opportunity was not to replace the speculum itself, but to enhance its performance in situations where visualization can be compromised.

Had the product not been developed, providers would have continued relying on improvised techniques that can increase examination difficulty and variability. The JFord Speculum Sleeve™ sought to provide a purpose-built solution for a challenge that had long been accepted as part of clinical practice.

Because the device entered a regulated healthcare market, development also required navigating the FDA review process. The product ultimately received FDA clearance for sale on **March 6, 2026**, representing a significant milestone for both the product and the newly formed company behind it.

Who the Product Serves

The primary users of the JFord Speculum Sleeve™ are gynecologists and other women's healthcare providers performing pelvic examinations in outpatient clinical settings. Healthcare facilities purchasing the product ultimately support clinicians who require reliable visualization during routine exams.

In a standard examination, a vaginal speculum is inserted and opened vertically to separate tissue and allow visual inspection of the cervix. In some patients, however, lateral tissue can move inward between the opened blades, reducing the clinician's line of sight.

The device was designed to address this specific workflow challenge. It needed to:

- Fit onto commonly used medium and large speculums already in practice;
- Be inserted comfortably before the speculum was opened;
- Expand without interfering with normal examination technique;
- Create lateral displacement of tissue to help maintain the visual field.

These requirements meant the product's usability was inseparable from its clinical effectiveness. The solution had to integrate naturally into established examination procedures while satisfying FDA expectations for safety and performance.

Business Context

For Ford MedTech, the JFord Speculum Sleeve™ represented more than a new product—it became the company's inaugural offering and the realization of Dr. Ford's vision to address an unmet clinical need she had witnessed firsthand.

Like many startup medical technology ventures, the project operated under meaningful constraints. Budget considerations required efficient use of development resources, while regulatory timelines created pressure to maintain momentum and avoid costly delays.

Ford MedTech's lean structure meant that Nexus became far more than a contract design firm. Nexus served as a trusted product realization partner, helping guide decisions across engineering, manufacturing, testing, and supplier engagement, while supporting regulatory preparation.

For a first-time product company, that continuity helped transform an early concept into a commercially viable medical device.

Key Constraints

Several constraints shaped the project from the outset.

Dr. Ford had previously worked with another design firm to secure intellectual property protection, establishing a patented product concept before Nexus became involved. Those early patent decisions influenced both the overall form of the device and the manufacturing approaches available to the team.

The product also faced practical design challenges:

- A single sleeve configuration needed to accommodate a range of medium and large speculums.
- Inflatable components had to reliably maintain shape and performance during use.
- Materials had to satisfy biocompatibility requirements appropriate for patient-contact devices.
- Testing methods had to be developed to evaluate performance before clinical introduction.

These constraints ultimately drove innovation, forcing the team to balance usability, manufacturability, regulatory requirements, and patent considerations simultaneously.

Nexus's Role

How We Were Engaged

Nexus joined the project after the initial concept had been established but before the device had been engineered into a manufacturable product.

The team assumed responsibility for most aspects of product realization, including:

- Product design;
- Mechanical engineering;
- Rapid prototyping;
- Verification testing;
- Design for manufacture and assembly;
- Cost engineering;
- Manufacturing strategy;
- Vendor and supply chain sourcing.

Nexus also supported Ford MedTech's regulatory efforts, working closely alongside regulatory consultant Michele Jans and quality consultant Larry Pope.

Rather than executing a narrowly defined phase of development, Nexus functioned as an extension of the Ford MedTech team throughout the journey from concept refinement to launch preparation.

The Specific Challenge We Were Solving

When Nexus became involved, Dr. Ford had identified the clinical problem and established an overall design direction, but several critical questions remained unanswered.

The team needed to determine:

- How to create sufficient lateral tissue displacement while preserving cervical visibility;
- How to maintain tension within the device as the speculum opened;
- How to securely attach the sleeve to a variety of medium and large speculum designs;
- How to integrate inflatable pouches for additional tissue management;

- How to manufacture the product consistently and at scale.

Each of these issues carried technical, usability, and manufacturing implications. Solving them required repeated cycles of prototyping, testing, and refinement.

How We Worked

Concept Viability and Strategic Framing

Dr. Ford's years of clinical experience provided strong confidence that the underlying problem was real and significant. As a result, Nexus was not tasked with validating the existence of the need itself.

Instead, the focus became determining whether that need could be addressed through a practical, manufacturable, and regulatorily acceptable device.

The project was therefore less about deciding whether to proceed and more about identifying the best path forward.

Industrial Design and Human Factors

Early development centered on translating the patented concept into a device that clinicians could actually use.

Nexus generated manufacturing-oriented sketches and developed numerous in-house prototypes using RF welding techniques. These physical iterations allowed the team to evaluate fit, handling, deployment, and performance under realistic conditions.

One important discovery emerged during testing: the original patented configuration proved overly constrained on certain speculum sizes. To address this, Nexus incorporated a stretchable feature that improved adaptability across different instruments.

Material selection was also heavily influenced by biocompatibility requirements. Every design decision needed to consider not only performance but also patient safety and regulatory expectations.

The result was a product shaped as much by real-world usability as by engineering specifications.

Mechanical Engineering

The device's defining feature involved inflatable side pouches designed to displace tissue laterally during examinations.

Achieving this required solving several engineering challenges.

RF-welded seams had to withstand inflation without leakage while maintaining structural integrity under expected examination forces. Weld quality became critical to device reliability.

The team also developed manufacturing methods that positioned welded features inward, preventing exposed edges that could interfere with use.

Balancing these requirements demanded close coordination between design intent and manufacturing feasibility. Even small adjustments in geometry or assembly sequence could influence both usability and production success.

Manufacturing Strategy

Nexus worked closely with Ford MedTech to identify and evaluate manufacturing partners capable of producing the device consistently.

Because the development team had built numerous prototypes internally, Nexus could clearly communicate assembly methods and process requirements to potential suppliers. This knowledge transfer accelerated supplier onboarding and informed process improvements.

Manufacturers refined certain assembly techniques based on production expertise, including modifications to tube welding methods.

Initial tooling was developed collaboratively and optimized before transfer to the contract manufacturer.

Nexus also:

- Managed supplier relationships;
- Coordinated progress during early production activities;

- Reviewed samples and implementation changes;
- Sourced and supplied materials for pre-production builds;
- Continued supporting material procurement during initial manufacturing runs.

This hands-on involvement helped maintain design intent as the product transitioned into production.

Regulatory Strategy

Regulatory planning was incorporated throughout development rather than treated as a final checkpoint.

The device was ultimately reviewed by the FDA and determined to be **510(k)-exempt**, while still requiring robust documentation demonstrating safety and effectiveness appropriate to its classification.

Nexus supported regulatory activities by conducting the verification and validation testing required for submission.

During pre-submission interactions, the FDA identified additional testing considerations not originally anticipated by the development team. Nexus responded by creating test protocols, fixtures, and specialized evaluation equipment to generate the necessary evidence.

Among these tools was a simulated vaginal vault developed to evaluate device performance under repeatable conditions. This enabled objective testing that informed both regulatory submissions and design refinement.

The product ultimately received FDA clearance for commercial distribution on **March 6, 2026**.

Pre-Launch and Market Readiness

Transitioning from development to commercialization required work that extended beyond engineering.

Nexus coordinated pilot and pre-production builds while supporting the creation of market-ready deliverables, including:

- Product labeling;
- Packaging components;
- Box sourcing;
- Documentation necessary for launch.

Because these elements exist within a regulated environment, their development also required alignment with applicable FDA requirements.

The result was a product prepared not only for manufacture, but for commercial introduction.

Key Collaborations

The project's success depended on close collaboration between Dr. Ford and the Nexus team.

As both inventor and practicing gynecologist, Dr. Ford provided continual feedback on whether design refinements improved clinical utility.

Development became an iterative cycle:

Design → Prototype → Evaluate → Refine

Dr. Ford reviewed prototypes throughout the process and visited Nexus facilities to evaluate devices firsthand using test setups developed by the team.

That direct access to end-user insight accelerated decision-making and ensured that technical progress remained aligned with clinical priorities.

The Outcome

Product Impact

The JFord Speculum Sleeve™ successfully advanced from an early concept to an FDA-cleared medical device.

The development team achieved the goals established at the outset of the project:

- Transforming a concept into a manufacturable product;
- Addressing the intended use scenario identified by Dr. Ford;
- Incorporating design refinements that improved adaptability and usability;
- Completing verification and validation activities;
- Securing FDA clearance.

The finished product reflects numerous enhancements made throughout development that were not present in the original concept.

Business Impact for the Client

The JFord Speculum Sleeve™ became the inaugural product offering for Ford MedTech and marked the transition of the company from concept-stage startup to commercial medical device manufacturer.

Equally important, it enabled Dr. Ford to pursue a solution inspired directly by her clinical experience.

Rather than simply identifying a persistent challenge, Ford MedTech created a pathway to bring a purpose-built product into the marketplace.

User and Market Impact

Commercial sales of the JFord Speculum Sleeve™ are planned for fall and winter 2026.

As adoption begins, Ford MedTech will have the opportunity to gather real-world feedback from healthcare providers regarding product integration and user experience.

The launch represents the beginning of the product's market journey and an important milestone for a first-time medical device company.

What Made the Difference

Several factors contributed to the project's success, but one capability consistently changed the trajectory of development: the ability to rapidly prototype, test, and refine ideas in-house.

Because Nexus could move quickly from concept to physical evaluation, the team identified usability issues early, explored alternative approaches efficiently, and implemented improvements without lengthy development delays.

Combined with Dr. Ford's direct clinical feedback and the agility of a small, collaborative team, this iterative process accelerated progress while reducing uncertainty.

Ultimately, the project succeeded not because of a single breakthrough, but because the right expertise, the right partnership, and the ability to learn quickly were present at every stage of development.