

Innovation in Algorithm- and AI-Driven Medical Devices

Surgical Robotics and Non-Invasive Monitoring – From Technological Strategy to Safe Clinical Execution

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SVP Research and Development at Momentis Surgical, Cordio Medical

Shift in Care Model – From Hardware-Centric to Intelligence-Centric Devices

Presentation Objective

To demonstrate how we can:

- Innovate rapidly
- Integrate AI responsibly
- Maintain clinical safety
- Meet regulatory requirements

Through Two Depth Axes

- Surgical Robotics – Invasive device
- Non-Invasive Medical Monitoring

In both – the same principle

- Proper design and development enable safe use of AI Non-Invasive Medical Monitoring

Revolution Over the Past Decade

From traditional mechanical systems to intelligent platforms

Integration of:

- Advanced sensing
- Real-time algorithms
- True Artificial Intelligence
- Autonomous systems

Why Is This Important?

- Algorithms and AI are becoming an integral part of medical treatment
- Transition from "passive devices" to intelligent platforms
- Requires continuous balance between: Technology, Clinical practice, and Regulation

Momentis Surgical Achieved 9 FDA Approvals

The future of medical AI will not be defined by who builds the smartest model—but by who builds the safest, most trustworthy systems

Innovation and compliance are not opposing forces—they can reinforce each other



De Novo
1st Gen GYN



510(k)
Abdominal Access
Ventral Hernia
Repair



Tools and accessories for
our Gen 2 robot

Momentis Surgical – Innovation in Surgical Robotics

Anovo Technology – Key Advantages

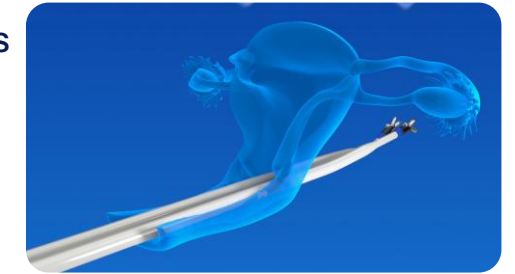


- Articulated arms with optimal range of motion
- Internal motion only – no external movement, improve patient recovery times
- Less invasive, less traumatic, cosmetically appealing – minimal scarring (transvaginal)
- Allow Retroflex/Antegrade
- Modular System for Single and Multi-Port
- Compact and lightweight system – occupies minimal space in the operating room
- Simplified setup and docking, improving workflow efficiency

Flexible Robot

First Axis: Innovation in Surgical Robotics

- Unique mechanical technology
- Advanced control algorithms
- Higher precision
- Improved stability
- Better clinical outcomes



Robotic Laparoscopy
Mechanized Straight Stick Instruments



Paradigm Shift: From Manipulating a Straight Stick to Manipulating Shoulder-Elbow-Wrist

Incremental Path Toward Autonomy

Surgical Robotics and Non-Invasive Monitoring – From Technological Strategy to Safe Clinical Execution – Modular Approval

Practical Regulatory Implementation

- Modular Approval
- Innovation in stages – breaking innovation into verifiable components
- Shortened development timelines
- Reduced regulatory risk
- Validation before expansion – approval of core functionality before AI extensions
- Integration of AI into the development process itself: Process optimization, Improved code quality, Risk reduction
- Project consolidation
- One platform, many products. Shared validation components
- Investment in compliance testing infrastructure



Result: Speed + Quality + Regulatory Compliance

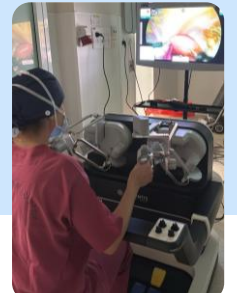
Central Engineering Challenges

- Hardware–software integration
- Risk management
- Testing: V&V, Usability, EMC/Safety
- Algorithm validation
- AI transparency – Explainability
- Testing and regulatory costs
- Development costs (inherent component)

Design for verification from day one

The Path Toward Surgical Autonomy

- Surgeon assistance
- Shared control
- Remote control
- Task-level automation
- Instead of a person holding a camera – a robotic arm controlled by the surgeon



Successful autonomy evolves in measured, verifiable steps

AI can accelerate development—if it's treated as a tool, not an authority

GitHub Copilot, OpenAI ChatGPT, Google Gemini, Snyk, SonarQube, Microsoft IntelliTest

♥ NON-INVASIVE - LOWER RISK

Cordio Medical – Groundbreaking AI-Driven Remote Monitoring Technology

Cordio's Differentiation Factors Include



Early Detection

Detection of early stages of decompensation in Heart Failure patients within 30 days before hospitalization, enabling early and more effective intervention



Software-Based Solution

Requiring only the patient's phone, thus provides continuous monitoring, anywhere and anytime, without requiring training, operational expertise or capital expenses



Second Axis: Non-Invasive Medical Monitoring

- Transition to continuous medicine and Self-Management
- Integration of data sources: Physiological sensors, Medical records, Advanced Signal processing, AI-based intelligent algorithms
- From reactive medicine to preventive medicine
- Disease management similar to diabetes

6 sentences on the App Display for recording

Available in 5 different languages (EN, ES, AR, RU, HE)

User Flow



Using AI to Build Better Devices

AI does not replace engineers – it multiplies their effectiveness

AI Integration in the Development Process

- Accelerated development using AI
- Frontend code generation directly from Figma files
- Real-time code completion
- Automatic function scaffolding
- Automatic refactoring
- Testing and Quality
- AI-assisted Code Review
- Automatic Unit Test generation
- Intelligent Static Code Analysis

Guiding Principle:

AI generates + Engineer validates

Unique Challenges of Medical AI

- Data collection
- Data quality for training
- Validation – requires large quantities of labeled data
- High cost of clinical trials
- Bias
- Generalization to different populations
- Real-world performance monitoring
- Reassessment throughout the product lifecycle – Post-Marketing outcome

Development for Validation

- Agreement on clinical trial design with regulatory authority
- Investment in infrastructure and tools to improve accuracy
- Consideration of cloud costs
- Investment in performance for large data execution
- Performance testing
- Validation against clinical data

Lifecycle Performance Management

Monitoring AI must be managed as a living system, not a one-time release

Figma → AI → Frontend Code → Tests → Review → Release

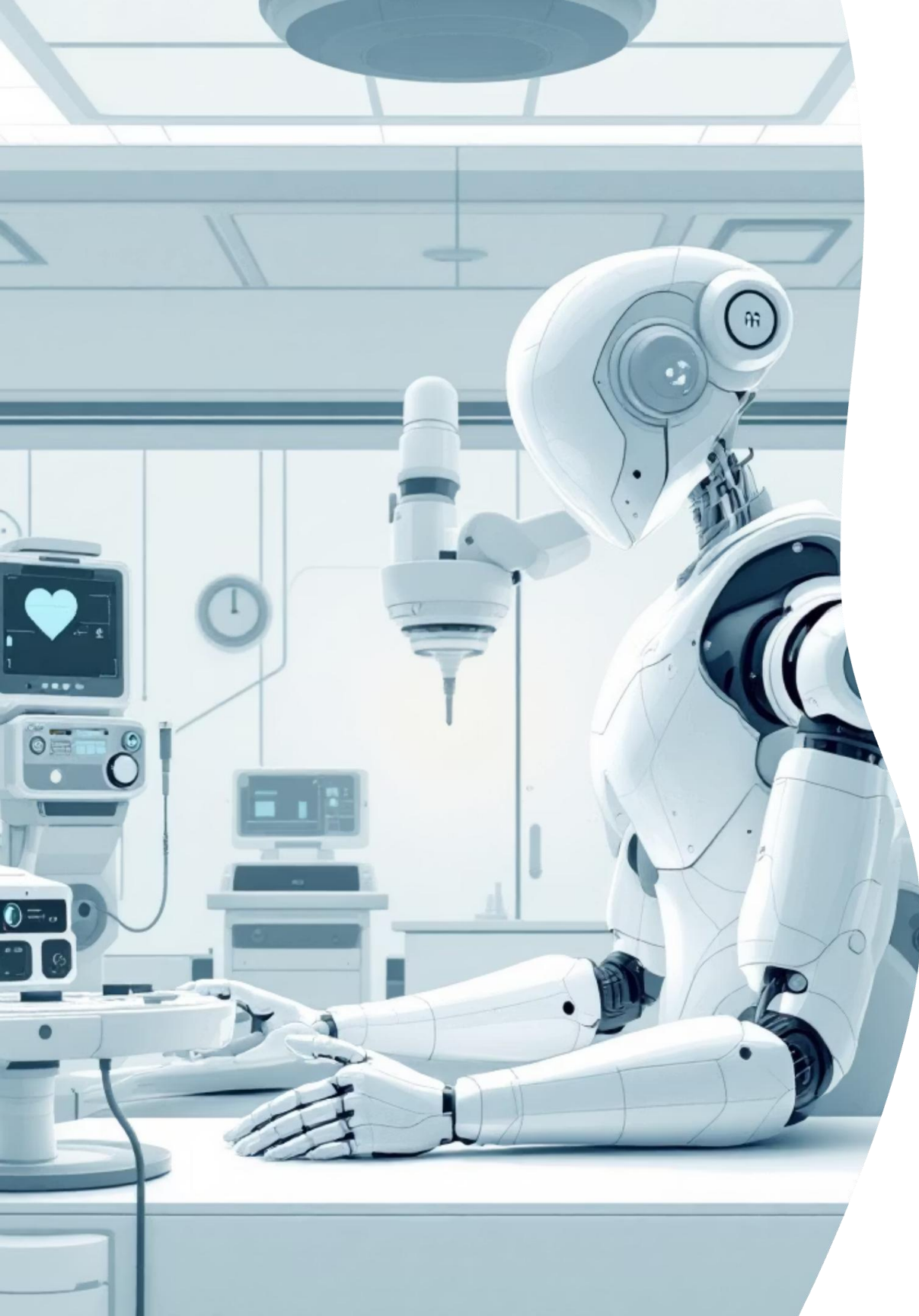
Where Medical AI Is Headed

The future of medical AI will not be decided by the smartest model, but by the safest and most trustworthy system

- **True innovation is built on strong engineering foundations**
- Regulation is not a barrier – it is a mechanism of quality and trust
- **Strong foundations before everything**
Engineering, clinical and proper architecture
- **Incremental innovation**
Validation → Clinical value → Small steps
- **Design for Verification**
- **AI is part of a system** – not a magic component
- The winners of the coming decade will be those who know how to integrate: AI + Engineering + Clinical practice + Regulation
into one trustworthy system

- AI does not replace clinical judgment – it enhances it when built correctly

Start with strong foundations · Innovate incrementally · Design for verification · Treat AI as part of a system, not a magic component



Thank You