

WHITE PAPER

Beyond Off-the-Shelf: What It Really Means to Build a Custom Arm.

A deep dive into custom arm configurations engineered on Kinova's medical-grade actuator platform.

FOR MEDICAL DEVICE TEAMS MOVING FROM VALIDATED CONCEPT TO PRODUCT

MEDICAL-GRADE ROBOTICS

The Right Arm at the Right Time

Robotics shouldn't be our medical device partners' core business. Building safe, effective, commercially viable devices is.

That is precisely why most medical device partners come to us for actuators and arms rather than building their own: it lets them spend their engineering budget on the parts of the product that truly set it apart, while we handle components that are just as critical but far less distinctive, including the manipulator that moves, senses, and operates safely.

Engineering services aren't our core business either. We didn't set out to become a contract engineering house. But enough partners reached a point where an off-the-shelf arm no longer fit and the geometry, interface, or footprint needed to be designed specifically around their product. In response, we built a dedicated capability around custom arm configurations engineered using our medical-grade actuators.

This white paper provides an in-depth, technical look at what that involves: why we still recommend starting with an off-the-shelf arm, what "custom" really means when it's built using proven actuators, what it costs and what it provides, how the engagement works day to day, and how to determine whether your program has reached the point where custom is worth considering.

KEY TAKEAWAYS

- **Start off the shelf.** Speed, cost discipline at the riskiest stage, and lower integration risk all favour a standard medical-grade arm for a v1.
- **Programs earn their way into custom.** The trigger is a real, specific constraint — not a general sense that custom sounds more advanced.
- **Custom is not a clean-sheet robot.** Safety functions, diagnostics, real-time communication and cybersecurity are inherited from a proven actuator family.
- **It is structured as a co-development program** with clearly divided responsibilities, staged hardware maturity, and documentation treated as a deliverable.

The Case for Starting Off the Shelf

We'll say this up front, even though it's not the pitch you might expect from a document about custom engineering: for a first-generation product, start with an off-the-shelf arm.

There are three reasons this isn't just caution talking.

1 Speed

An off-the-shelf medical-grade arm is available now. It already comes with an established safety architecture, certifications and pre-certifications, and a documentation base that would otherwise need to be developed from scratch for a custom build. For a program racing toward its first system integration milestone or usability study, that head start is often the difference between hitting a date and missing it.

2 Cost discipline at the riskiest stage

Early-stage programs are, almost by definition, still validating assumptions about the procedure, the workflow, the market, and sometimes the entire concept. A custom mechanical arm is a bet on a specific geometry and set of requirements. Placing that bet before those requirements are stable means paying for a redesign later, on top of the original cost.

3 Lower integration risk

A standard platform has already been integrated into other systems, has known failure modes, and is supported by a team that has already answered most of the questions a new integrator will ask. That accumulated experience reduces the number of unknowns your team has to resolve on its own.

None of this is a knock on custom engineering. It's a recognition that the value of "built specifically for you" only shows up once you know what "for you" means in enough detail to design against it.

| Two Very Different Bets

The choice between a standard platform and a custom configuration is not a choice between good and better. It is a choice about when to make that investment.

	CUSTOM FROM DAY ONE	STANDARD PLATFORM FIRST
Question it answers	Is our specific geometry right?	Does the concept work at all?
Availability	Designed, built and qualified for you	Available now
Compliance groundwork	Developed alongside your program	Safety architecture, certifications and documentation base already in place
Integration risk	Unknowns initially resolved by your team	Known failure modes, prior integrations, support organization
Principal risk	Paying for a redesign if requirements shift	Standard geometry may constrain later generations
Right when	Requirements are stable and validated	Concept, workflow and market validation are still open

Off-the-shelf hardware defers the custom investment until the requirements are actually known. That is its central advantage, and it is why we recommend it even when it means less engineering work for us in the short term.

| Where the Calculus Changes

The pattern we see most often looks something like this: a team validates its concept on a standard platform, gathers initial usability or clinical feedback, secures the funding or internal commitment for a second generation, and only then finds that the standard geometry has become the constraint rather than the accelerator. Concretely, that constraint shows up in a handful of recurring ways.

Programs earn their way into custom arm territory rather than starting there.

01

Reach and workspace

The envelope doesn't quite match the geometry of a specific procedure or operating environment.

02

Payload or torque

Joint loads or torque requirements that a general-purpose arm was never optimized for.

03

Tool or instrument interface

An interface that needs to be purpose-built rather than adapted.

04

Footprint and industrial design

Constraints driven by the rest of the system — a cart, a boom, a fixed mount, a sterile field.

05

Degrees of freedom

The application needs fewer, simpler joints — or a different kinematic arrangement entirely.

06

Program economics

Custom carries real cost in labour, tooling and qualification hardware. It makes sense once a program can absorb that investment.

When one or more of these becomes a real limitation, not a hypothetical one, that's usually the signal it's worth having the custom conversation.

What “Custom” Actually Means at Kinova

A custom arm configuration is not a clean-sheet robot, and that distinction is exactly what determines how fast our partners get to market. “Custom robotic arm” means very different things depending on who’s building it, and the difference shows up directly in program timelines and risk.

We can design a fully custom actuator (new motors, gearing, safety electronics, firmware) or develop a custom arm configuration using our proven, off-the-shelf actuator family. We don’t recommend the fully custom route, for the same reason we don’t recommend a clean-sheet robot: it reintroduces the multi-year, high-risk development cycle our partners are trying to avoid, forfeits the field-proven reliability already built into our actuators, and takes them even further from their goal. The safety functions, diagnostics, communication, and hardening below are already built in and ready to reuse from day one.



The result. A mechanism shaped around your product, built from components with an established track record.

Not the alternative. An arm that asks your product to adapt to it, or a clean-sheet design that has to prove itself from scratch.

| Who Owns What

We structure custom arm programs as genuine co-development, with clearly divided responsibilities rather than a vague “we’ll figure it out together.”

Division of Responsibilities	
TYPICAL CUSTOM ARM PROGRAM	
YOUR TEAM OWNS	
Requirements	What the arm has to meet
Clinical use	How it is used, by whom
System integration	How it connects to the rest
Regulatory strategy	Pathway and submission
KINOVA OWNS	
Arm-level design	Mechanical and electrical
Safety and risk analysis	Arm and actuator level
Verification work	Demonstrating that the design meets specifications
Manufacturing	Medical robotics production

That division isn’t just organizational tidiness. It reflects where each party’s expertise lies.

You understand your procedure, your users and your regulatory strategy better than anyone. We understand actuator-level safety architecture, arm dynamics and medical robotics manufacturing better than anyone.

Keeping the lines clear lets both teams move quickly without stepping on each other. It also ensures that the evidence you receive can be used directly, rather than reconstructed later.

Frameworks Commonly in Scope

IEC 60601	Electrical and EMC safety
ISO 14971	Risk management across the device lifecycle
IEC 62304	Medical device software lifecycle processes

Test Responsibilities

Verification is conducted against the standards applicable to your product and market. Responsibilities are assigned according to who is best positioned to perform each test and are defined explicitly at the start of the program rather than negotiated when a test date arrives.

| How the Engagement Runs

The work unfolds in stages rather than arriving as a single deliverable at the end.

PROGRAM STAGES



Changes are inexpensive before detailed design starts and costly afterward. Regular design reviews are conducted throughout all three stages.

Hardware maturity increases throughout the engagement. Early units support subsystem-level integration, proving that the arm works inside your broader system before every detail is finalized. Later units are built to a higher level of maturity and are ready for your own formal verification and validation. Both teams can therefore identify integration issues early, when they can be addressed through a design review rather than costly retooling.

Documentation accumulates alongside the hardware rather than being reconstructed afterward. These documents are treated as deliverables in their own right because your regulatory submission and downstream engineering will depend on them:

- | | |
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| <p>01 Requirements documents
Design inputs, agreed and versioned.</p> | <p>02 Compliance and traceability matrices
Requirements linked to the evidence demonstrating that they have been met.</p> |
| <p>03 Interface control documents
The mechanical, electrical, and control boundary, documented.</p> | <p>04 Mechanical and electrical drawings
Including electrical assembly drawings.</p> |
| <p>05 Bills of materials
Manufacturing-level definition of the configuration.</p> | <p>06 Design review records
Decisions and rationale, milestone by milestone.</p> |

What This Costs and What It Buys

We won't pretend custom engineering is cheap, and we don't think it's useful to imply otherwise.

The investment is real

Design and verification labour

Engineering time across definition, detailed design, and the verification activities that demonstrate the design meets its requirements.

Prototype hardware

Material costs for units across multiple iterations, from early integration builds to units ready for formal verification.

Tooling and qualification

Jigs, calibration systems and measurement equipment that a standard product purchase simply doesn't require.

WHAT THAT INVESTMENT BUYS

- An arm that fits your product instead of a product that fits an arm.
- A component base with a genuine safety and reliability track record instead of one that has to establish that record from scratch.
- A documented, traceable engineering process that supports rather than complicates your regulatory pathway.

For a program that's already validated and adequately funded, that trade is usually a good one.

For a program that's still finding its footing, it usually isn't — yet.

| Deciding If You're Ready

A few honest questions tend to separate programs that are ready for a custom arm conversation from those that would be better served by staying on a standard platform a little longer.

01 **Has your core concept been validated beyond early prototypes, clinically, commercially, or both?**

The question is not whether it performs well in a demonstration, but whether the workflow has held up in front of the people who will use it and the people who will buy it.

02 **Are your requirements stable enough that a design built against them today won't need to be substantially redone in six months?**

Workspace, payload, interface, footprint. If any of these is still changing, the custom design will need to change with it.

03 **Does your program have the funding and timeline to absorb a genuine engineering investment, not just a parts purchase?**

Design and verification labour, prototype hardware across iterations, tooling and qualification equipment.

04 **Is the limitation you're running into with a standard arm a real, specific constraint?**

Not a general sense that "custom" sounds more advanced. Name the constraint, in numbers if you can.

If most of those answers are yes, it's worth having the conversation. If they're not yet, that's a perfectly good answer too – standard platforms exist precisely so you can keep building without every answer needing to be yes on day one.

A Deliberate Step, Not a Default

Start off the shelf, and treat a custom arm configuration as a deliberate step you take once your product has earned it. When that point arrives, we'd rather build it with you on a proven actuator foundation than have you start a robotic arm program from a blank page.

→ Run your program through the four questions on **page 10**

→ Discuss with us whether custom is the right next step for your program

→ Or keep building on a standard medical-grade platform for now

TALK TO OUR ENGINEERING TEAM

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KINOVA



About

Kinova was founded on a simple but powerful idea: robotics should expand human potential. Inspired by assistive technologies developed to help family members living with muscular dystrophy, co-founder and CEO Charles Deguire helped transform that vision into a global robotics company focused on building technologies that empower people and advance medical innovation.

Talk to Our Experts

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