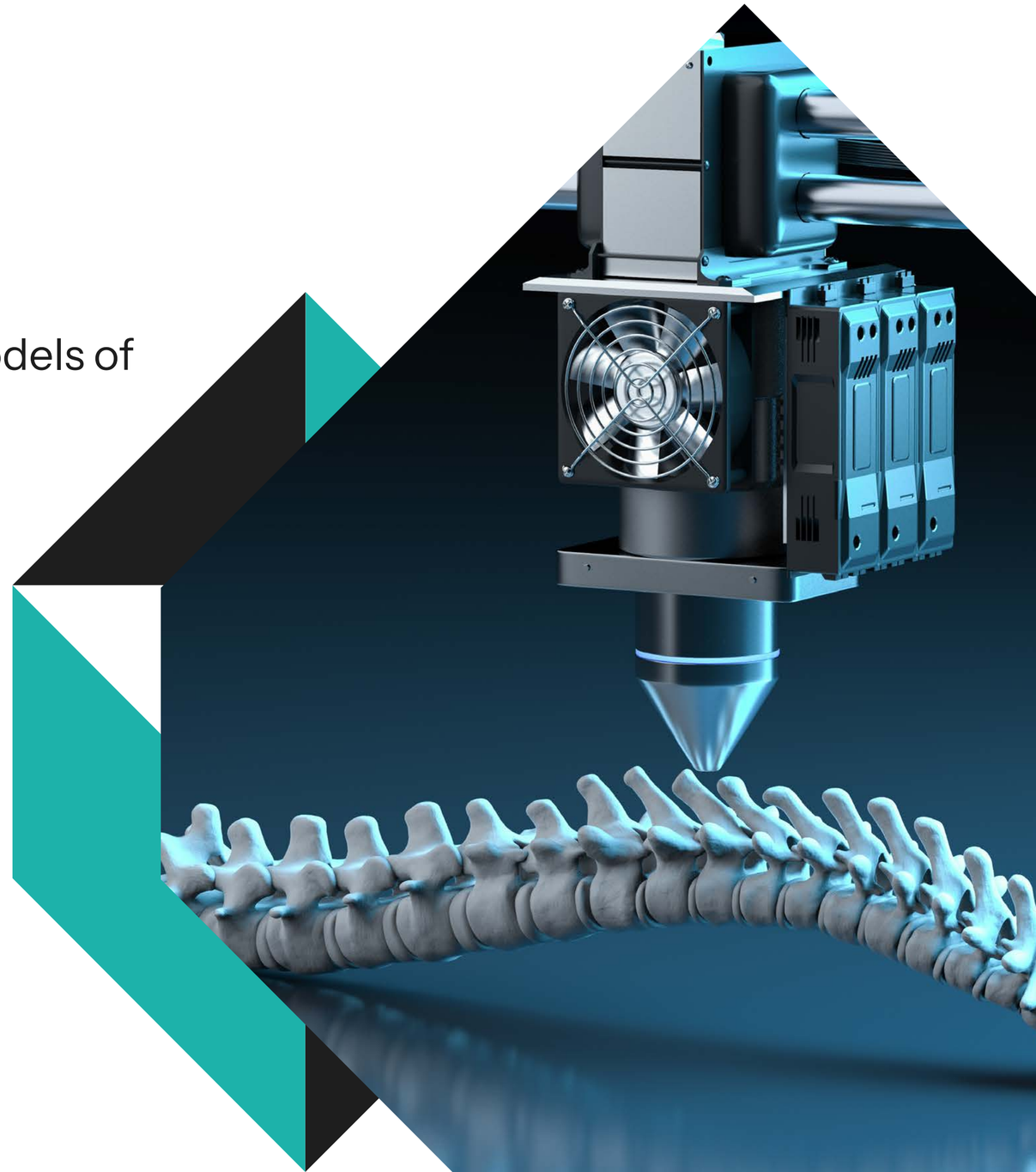
Stellarix

eBook

How Personalized Implants are:

- Rewiring Supply Chains and Operational Pricing Models of MedTech Firms
- Bringing Value for Hospitals, HCPs & Patients



www.stellarix.com

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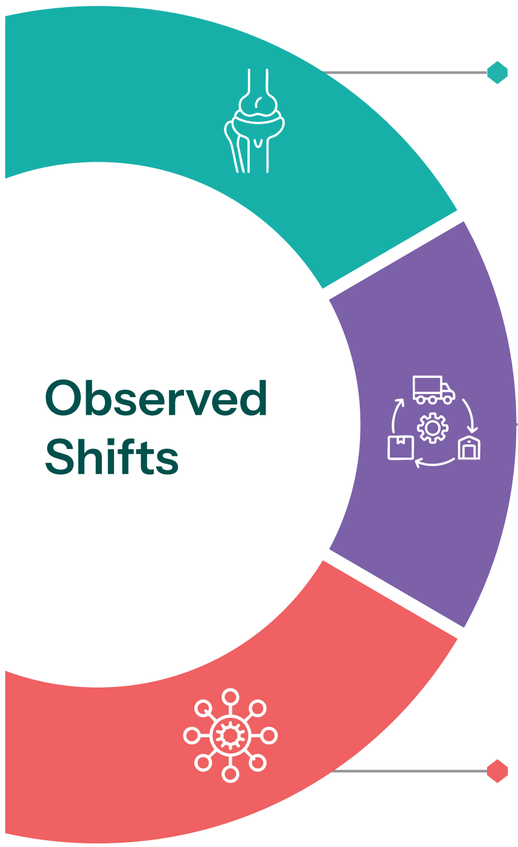
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Transition from Make-to-Stock (MTS) to Make-to-Fit (MTF)

Orthopedic manufacturing is undergoing a structural shift. 3D printing is redefining the orthopedics supply chain from centralized control to distributed intelligence. The design ownership, IP, and production, once confined to OEM plants, are now shared across digital and local nodes.

While 3D-Printed Lattice Structures have brought the following value proposition to the patients & healthcare providers (HCPs)



Personalization at Scale

Demand for patient-specific, digitally validated implants is redefining how products are designed, approved, and delivered

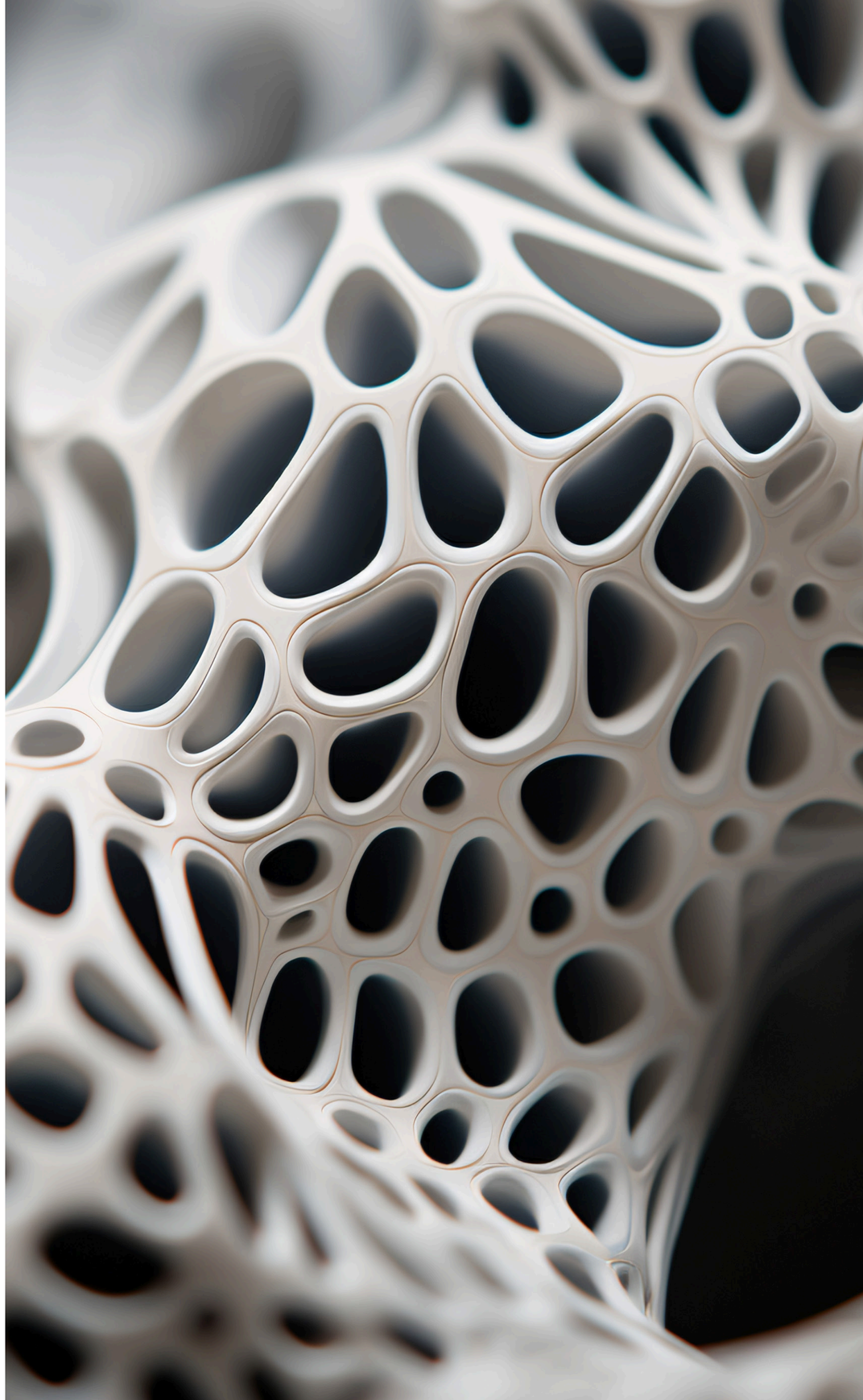
Agility over Volume

The shift from standardized mass production to variable, high-mix, low volume workflows introduces challenges in design validation, and vendor coordination

Decentralized Control, with Joint Accountability

As printing and finishing move closer to the point of care, OEMs face a new question: how to retain design integrity, quality assurance, and regulatory control across a distributed network

the transition from Make-to-Stock (MTS) to Make-to-Fit (MTF) has reshaped how MedTech firms manufacture, price, and capture value.





Top Three Models in AM Supply Networks

Model 1 Centralized Design, Distributed Printing

In this model, OEMs (or their design partners) keep control of digital design, its validation, and regulatory responsibility. Certified partners print the implant close to the hospitals.

Advantages	Supply Chain Orchestrators	Expected Future Leaders	Exemplary Current Players
Keeps design control with the OEMs but saves time and cost by printing closer to the patient's or hospital's location.	Own the digital thread, license prints, and ensure compliance.	Digital platforms owners (e.g., Materialise, Axial3D) may act as "design clearing houses" between hospitals and print hubs.	Stryker AMagine™: Offering central design, with regional AM partners in Michigan & Cork.

Model 2 Regional / Point-of-Care Hubs

In this model, printing occurs near or within high-volume surgical centers or hospitals, which are usually a joint setup among the OEM, the hospital, and the 3D-printing partner.

Advantages	Supply Chain Orchestrators	Expected Future Leaders	Exemplary Current Players
Rapid turnaround, surgeon co-design.	Currently led by OEMs and contract manufacturers, or by hospital partnerships (like LimaCorporate + HSS).	The future may see hospital-integrated additive labs acting under OEM licensing.	LimaCorporate + HSS ProMade Center (NYC).

Model 3 Hybrid Networks

In this model, OEM performs some 3D printing in-house (for control and R&D) but outsources additional work, such as large batches, surface finishing, or sterilization.

Advantages	Supply Chain Orchestrators	Expected Future Leaders	Exemplary Current Players
Flexibility and scalability of networks.	OEM retains master control but builds a "federated supply chain."	Platform orchestrators (e.g., Siemens Digital) may provide software backbones for hybrid ecosystems.	DePuy Synthes expanding hybrid AM footprint via EIT, TRS acquisitions.

How Leaders are Re-Designing AM Operations

Case Study

LimaCorporate + Hospital for Special Surgery + EOS

Exemplary Model 2:

In 2021, LimaCorporate (Now Envois Surgical) and Hospital for Special Surgery (HSS) established the first point-of-care 3D printing center for personalized orthopedic implants. The ProMade PoC Center, located within HSS, integrates Lima's validated design and EOS System's powder-based additive manufacturing workflows to produce patient-specific implants on site.

Co-Innovation Model:

- **Embedded Partnership:** Lima engineers and EOS printers operate within HSS under OEM quality controls.
- **Clinical Co-Design:** Surgeons and engineers jointly optimize the geometry and fit of customized implants.
- **Regulatory Alignment:** HSS's ProMade center functions as an FDA-regulated facility for designing customized implants on hospital grounds, the first of its kind.

Final Impact:

- **Lead Time Reduction:** Custom implant turnaround reduces to 5–7 days from 3–5 weeks.
- **Inventory Efficiency:** Eliminates international shipping and rework, reducing logistics cost by ~25%.
- **Precision:** Improved anatomical matching in complex reconstructions.
- **Scalability:** Establishes a precedent for decentralized, OEM-controlled supply nodes near surgical demand centers.



What Keeps MedTech Leaders Cautious

Cost & Yield Uncertainty

Models 1 & 3

Margins hinge on unpredictable material utilization, print yield, and post-processing rework rates. Difficulty in prediction of full-cost visibility.

Loss of IP / Oversight

Models 1 & 3

Concerns over data leakage, version control, and design ownership while distributing digital designs to external or remote print hubs.

Regulatory Ambiguity at Point-of-Care

Model 2

Challenges in ascertaining manufacturer's liability as hospitals act as manufacturing sites; blurring the boundaries between FDA and MDR.

Data & Traceability Gaps

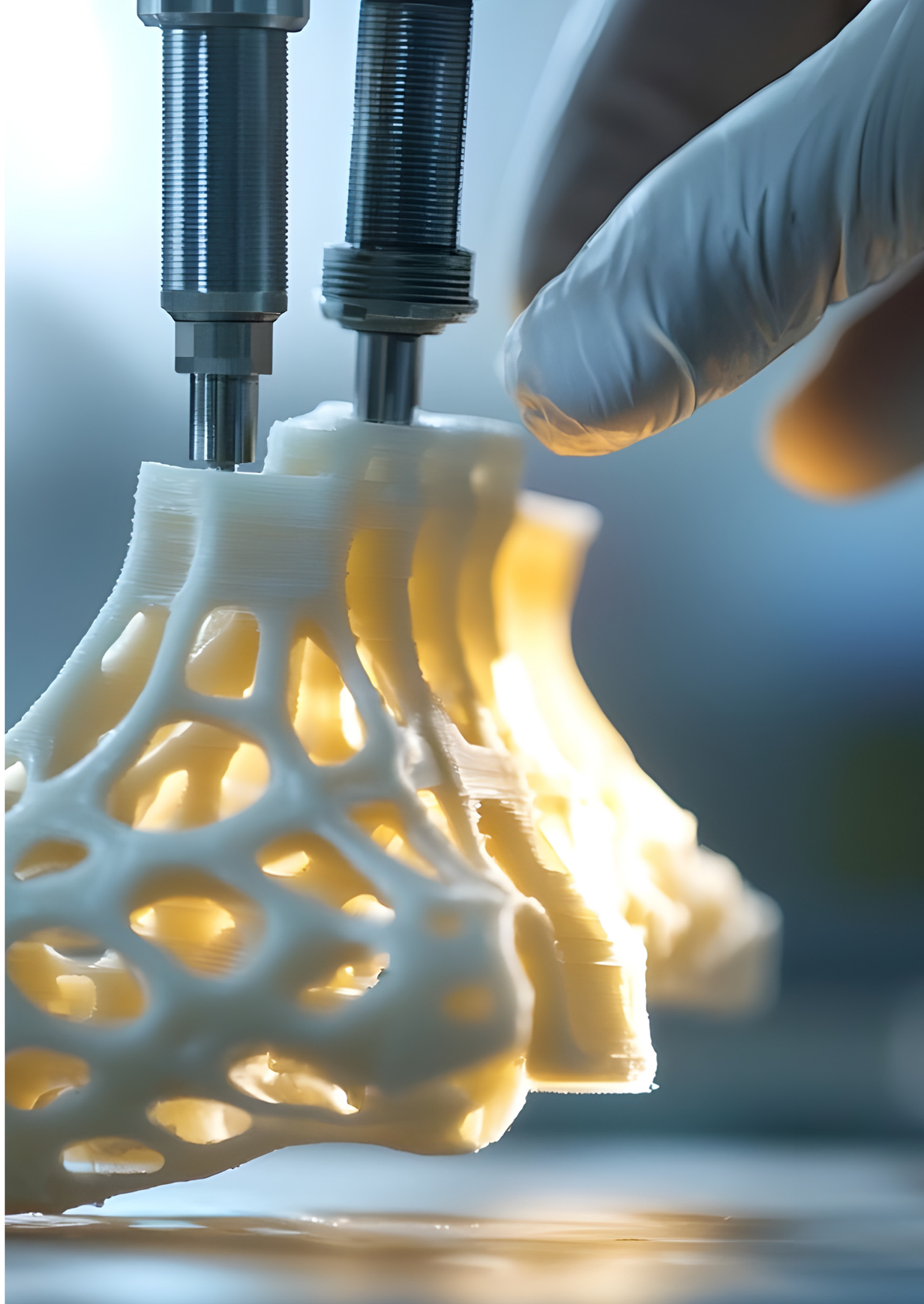
Models 1 & 3

Fragmented digital workflows and localized production can break device history records, complicating validation and recall readiness.

ROI and Scaling Risks

Models 2 & 3

Pilot programs deliver proof-of-concept, but scaling personalized implants across geographies often erodes expected ROI.



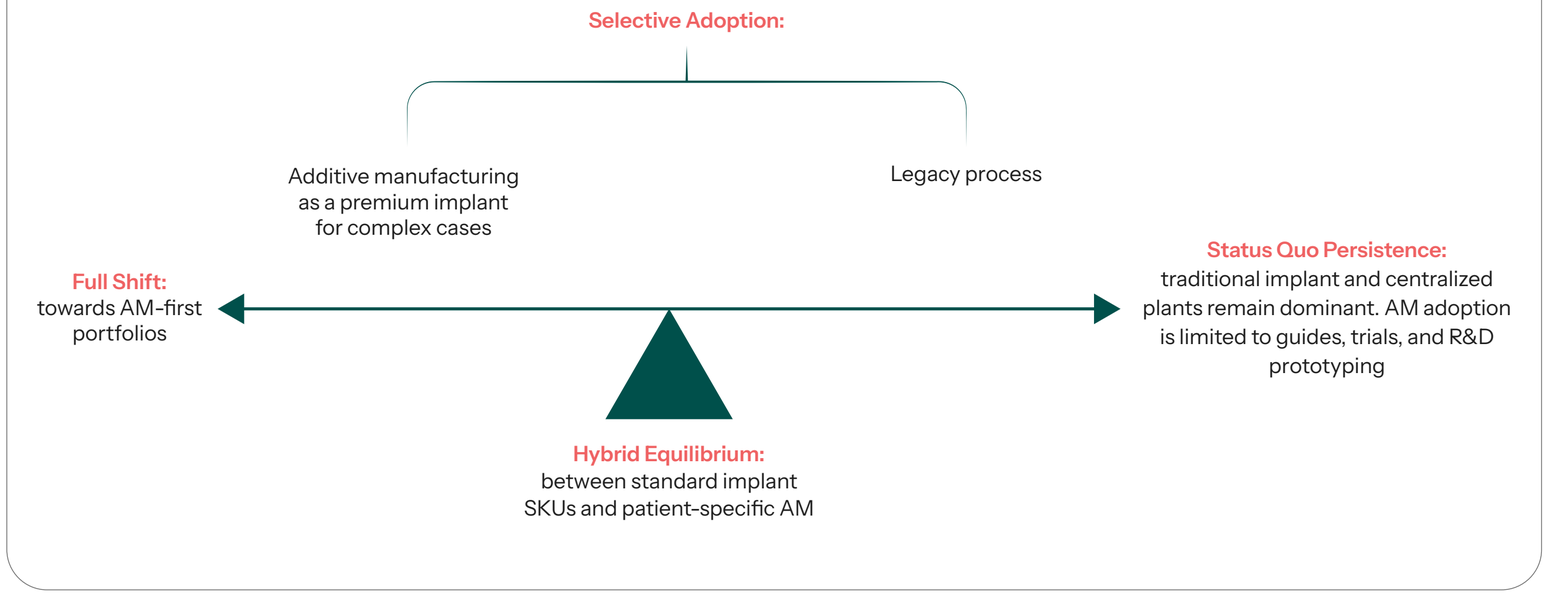


So What?

What's in it for MedTech Leadership, AM Device Manufacturers, Ecosystem Enablers, and Investors?

3D printing is migrating orthopedics from centrally controlled, SKU-intensive manufacturing to digital design–driven, distributed production with new validation workflows.

Going forward, the following four adoption scenarios could emerge:



Regardless of which scenario plays out, the implications are profound:

R&D cycles, supply-chain architecture, margin logic, and competitive advantage will be redefined. MedTech leadership, AM manufacturers, ecosystem partners, and investors must watch the developments and re-evaluate how they create, capture, and deliver value to the HCPs and to the Patients.

What Next?

As a next step, MedTech leadership, AM manufacturers, ecosystem partners, and investors should take the following measures:

Monitor Developments

3 developments to track

- Utilization & up-time of AM facilities across the globe
- Material qualification cycles and printer–material interoperability trends
- Regulatory precedents and supply-chain shifts

Avoid Actions

3 Actions to avoid when entering or expanding AM

- Piloting AM capacity for commodity implants, until scenarios are clear
- Scaling AM lines before establishing ROI breakpoints
- Running isolated AM pilots without integrating design workflow

Mitigate / Transfer / Minimize Risk

3 actions to keep investments safe

- Reposition excess AM capacity toward revisions, deformity, and low-volume processes
- In case of volume volatility, transfer co-manufacturing to the accredited AM bureaus for specialty prints

Looking to know more about personalised implants?

Stellarix supports MedTech leaders in monitoring AM shifts, avoiding misaligned investments, and mitigating risks across technology, supply chains, and partnerships. We provide research, intelligence, and strategic guidance to ensure every AM move is informed, disciplined, and future-proof.



About us

Stellarix Consultancy Services

Trusted partner in future-readiness, from idea to impact.

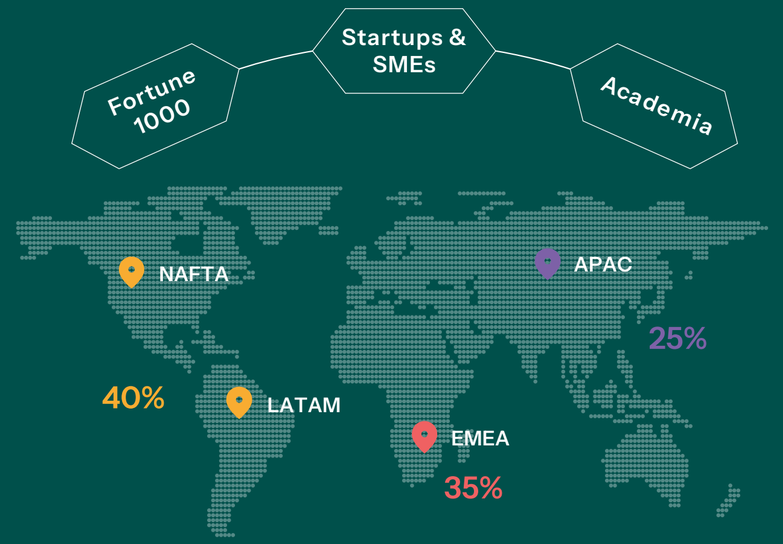
As an advisory and consulting company, our main focus is sustainable growth through critical innovation and commercialization. With more than 15 years of innovation research experience, we enable sustainable business growth by bringing together non-traditional and non-conventional consulting approaches.

Stellarix

Who We Are?

We offer consulting services to make businesses future-ready and improve goals and strategies with innovative solutions.

- 2000+ Annual Engagement Enquiries
- Presence Across 8+ Industries
- Deep Understanding of Emerging Tech
- 1000+ Global Stakeholders Across Geographies, Hierarchies, & Divisions
- Partnered with Clients from 50+ Countries



HQ | Jaipur, Rajasthan, India

Our Experience

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- Expert Network (KOLs) — **500K+ and Growing**
- Partners Supported — **500+**
- Consulting & Advisory Team — **250+ and Growing**
- Engagements Delivered — **16000+**

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