

SurgNow™: On-demand Manufacturing Of Surgical Instruments

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Objective

The SurgNow™ system:

- Addresses gaps in surgical readiness and instrument availability during forward or austere operations.
- Enables on-demand, distributed manufacturing for rapid production, inspection, and qualification of instruments directly at the point of use under Good Manufacturing Practice (GMP) and Quality Management System (QMS) standards.

Goal

To reduce logistical vulnerability, enhance operational autonomy, and transform surgical capability in remote, contested, or resource-constrained environments.

Technology

Self-contained production system for FDA-approved instruments integrating:

- Additive manufacturing
- In-line inspection
- Digital process monitoring and traceability
- Certified medical device quality system oversight

Designed for point-of-care production of sterile-ready surgical instruments.

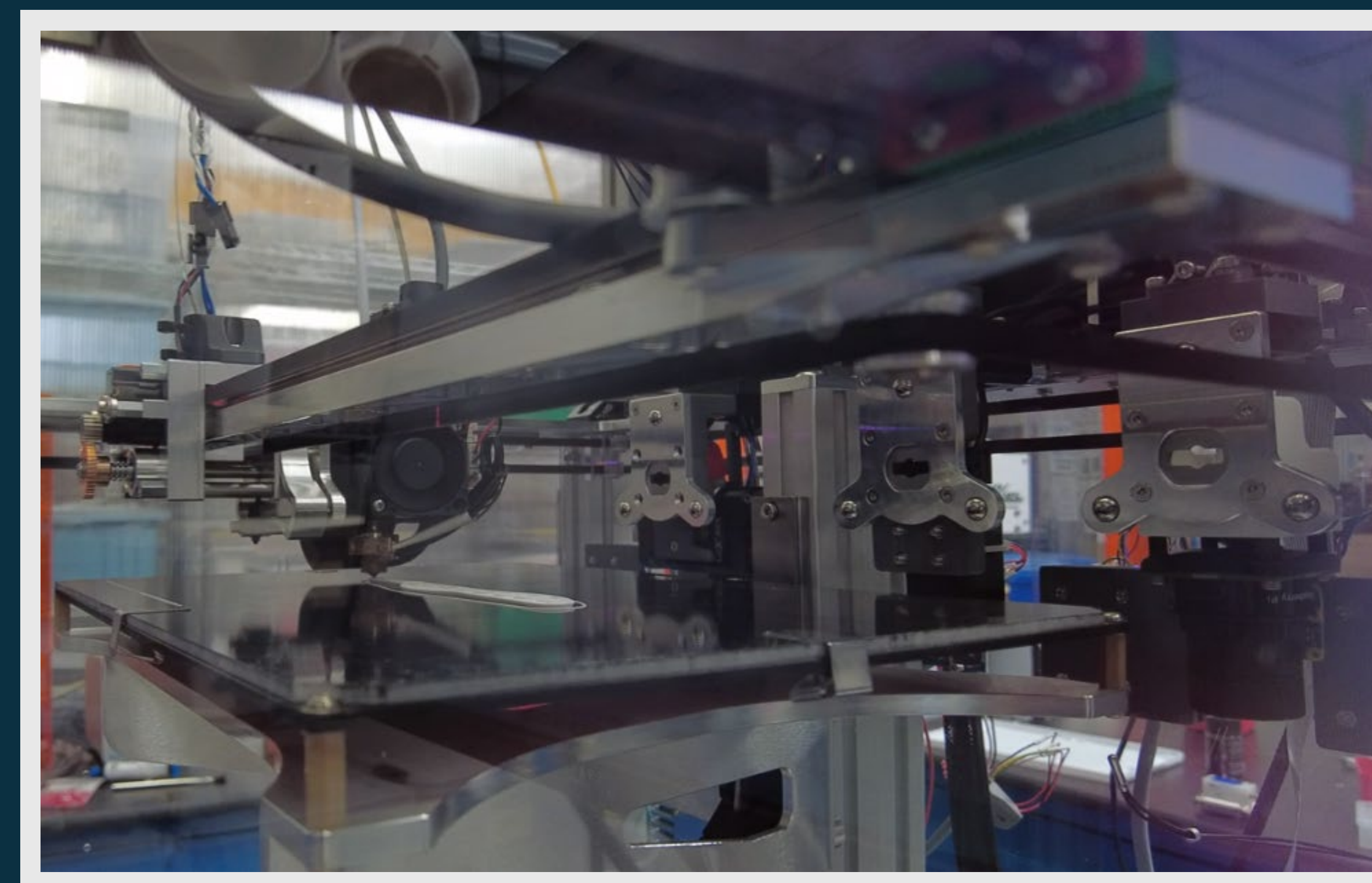


Fig 1. The SurgNow™ printer developed by Critical Innovations

Preliminary Results

- Prototype platform developed and operational (Fig 1)
- Instrument prototypes undergoing performance refinement (Fig 2)
- Operates with certified medical device quality framework
- Benchtop testing and validation studies planned

User evaluation studies

- Ex-vivo models
- Live-tissue models (IACUC approved)
- Cadaveric models (IRB approved)

Future Directions

- User interface refinement
- Sterilization protocol development
- Field-ready packaging
- Regulatory transition (Class 510(k)-exempt instruments)
- FDA clearance pathway for commercial distribution
- Validation under field conditions



Fig 2. SurgNow™ printed instruments made from various thermoplastics