UNIVERSITY OF NIS FACULTY OF MECHANICAL ENGINEERING

THE TENTH INTERNATIONAL CONFERENCE
TRANSPORT AND LOGISTICS
https://doi.org/10.46793/TIL2025.110V

til 2025

INTEGRATING SMART INFORMATION SYSTEMS AND THE INDUSTRIAL METAVERSE IN MEDICAL DEVICE PRODUCTION AND LOGISTICS

Nikola VITKOVIĆ[1], Milan MITKOVIĆ[2], Marek CHODNICKI[3], Milica BARAĆ[1], Aleksandar TRAJKOVIĆ[1]

[1] *Faculty of Mechanical Engineering, University of Niš, Serbia*
[2] *Faculty of Medicine, University of Niš, Serbia*
[3] *Gdańsk University of Technology, Poland*

ORCID iDs: *Nikola VITKOVIĆ* https://orcid.org/0000-0001-6956-8540
Milan MITKOVIĆ https://orcid.org/0000-0002-2800-9790
Marek CHODNICKI https://orcid.org/0000-0001-9471-5557
Milica BARAĆ https://orcid.org/0000-0002-5355-693X
Aleksandar TRAJKOVIĆ https://orcid.org/0009-0006-1390-8167

Abstract

The increasing demand for customized medical devices has driven the need for highly integrated, data-driven, and adaptable production and logistics systems. Traditional approaches no longer suffice for patient-specific implants, which require rapid design cycles, strict regulatory compliance, and precise coordination among clinical teams, engineering departments, manufacturing operations, sterilization units, and hospital logistics. Smart Information Systems (SIS) that incorporate IIoT, digital twins, AI analytics, and enterprise platforms have become essential for managing these complex workflows. When combined with Industrial Metaverse technologies such as immersive XR interfaces, multi-user collaboration environments, and persistent digital twins, a new paradigm emerges that connects physical and virtual operations across the entire medical device lifecycle. This paper presents a conceptual, integrated framework that illustrates how immersive collaboration, structured knowledge exchange, and real-time simulation improve design precision, manufacturing dependability, sterilization safety, and logistics efficiency, while supporting Industry 5.0 in healthcare manufacturing. These technologies enable a high level of accuracy, transparency, and human–machine interaction through virtual simulations.

Keywords*: Smart Information Systems, Metaverse, XR, Logistics, Manufacturing, Medical Device*

1 INTRODUCTION

Personalized medical devices are increasingly transforming modern healthcare by providing better anatomical fit, fewer complications, and improved long-term results. However, producing and delivering patient-specific implants remains one of the most complex workflows in healthcare manufacturing. Unlike mass-produced devices, personalized implants demand near-instant coordination among surgeons, biomedical engineers, manufacturing specialists, sterilization staff, and logistics teams. Each implant is unique, time-sensitive, and vital to patient care. Small delays or uncertainties in design, production, or shipping can directly impact surgical outcomes. Smart Information Systems (SIS) have emerged as a digital foundation to manage this complexity. By integrating AI-driven analytics, IIoT sensor data, ERP/MES systems, and regulatory traceability modules, SIS provides real-time visibility across the entire medical device lifecycle. Simultaneously, the rapid growth of the Industrial Metaverse introduces immersive, interactive environments where digital twins, humans, and production systems coexist. Through XR interfaces, surgeons and engineers can collaboratively examine anatomical models and implant designs, manufacturing teams can visualize build processes, and logistics coordinators can rehearse transport scenarios. These immersive interactions enhance traditional data dashboards with spatial understanding, intuitive collaboration, and human-centered decision-making. Despite notable advances in digital manufacturing and logistics, integrating SIS and Metaverse systems into medical production has not been sufficiently explored. This paper proposes a comprehensive framework that links clinical diagnostics, implant design, additive manufacturing, sterilization workflows, and hospital delivery within a unified digital-physical ecosystem.

2 LITERATURE REVIEW

Digital transformation in industrial and clinical settings has advanced significantly over the past decade. Smart Information Systems (SIS), the Industrial Internet of Things (IIoT), and digital twins are recognized as vital enablers of intelligent, data-driven production environments [1 - 4]. Digital twins facilitate real-time monitoring, process optimization, and predictive maintenance across manufacturing domains, offering detailed visibility into machine behavior and production workflows. In healthcare, digital twins have been applied to anatomical modeling, surgical planning, and implant simulation, though integration with production and logistics systems remains limited. Extended Reality (XR) technologies, such as VR, AR, and MR, have shown strong potential for manufacturing training, remote collaboration, and ergonomic assessment [5 - 7]. XR enhances spatial understanding, reduces cognitive load, and improves training outcomes. In medicine, XR supports pre-surgical planning, patient-specific implant evaluation, and tele-collaboration among clinical teams. The rise of the Industrial Metaverse combines digital twins, XR, AI analytics, and edge computing into persistent, multi-user environments [2, 7 - 9]. These immersive spaces enable real-time interaction with production systems, logistics, and digital documentation. Early implementations of the industrial metaverse demonstrated comprehensive visualization of factory layouts, machine states, and process simulations [8]. Such environments are especially relevant for medical production chains, where traceability, sterile handling, and cross-institutional coordination are critical. Although digital manufacturing and XR capabilities have developed rapidly, research in medical logistics provides equally important insights into the unique challenges of healthcare supply chains. Personalized implants require navigating complex delivery paths that involve a sterile chain of custody, time-sensitive routing, and strict environmental conditions. Gupta et al. [10] offer a thorough review of medical supply chain modeling approaches, emphasizing uncertainties, regulatory pressures, and the need for adaptive, intelligent logistics systems. Similarly, Kelle et al. [11] analyzed hospital and pharmaceutical supply chains, highlighting that healthcare logistics demand specialized coordination strategies, inventory policies, and risk mitigation mechanisms not typically found in general industrial logistics. These studies underscore the growing importance of integrating logistics intelligence into SIS and Industrial Metaverse frameworks to ensure the timely, safe, and sterile delivery of personalized medical devices.

3 METHODOLOGY

The methodology develops an integrated digital framework connecting Smart Information Systems (SIS), the Industrial Metaverse, and structured expert knowledge throughout the entire lifecycle of personalized medical device production and logistics. It traces the whole implant process, from clinical diagnostics to design, manufacturing, sterilization, packaging, transportation, and final surgical preparation, ensuring interoperability, real-time visibility, and immersive collaboration among all involved institutions. The process starts with clinical diagnostics and data integration, where CT, MRI, or X-ray images are segmented and reconstructed into patient-specific anatomical models. To ensure accuracy and traceability, all imaging data are exported in standardized formats (e.g., medical formats such as DICOM or STL for direct CAD) and imported into SIS platforms with authentication, version control, and metadata tagging. Because many implants are produced under urgent conditions, SIS automates file validation and routes anatomical data directly into engineering environments without losing fidelity. The next stage involves engineering design and manufacturing planning, where biomedical engineers create implant geometries using CAD, parametric modeling, and anatomical fitting. SIS provides access to regulatory data, past implant designs, and material constraints, keeping engineering decisions compliant and informed. The Industrial Metaverse allows surgeons and engineers to collaborate within an immersive XR environment, examining implant fit, curvature, and screw trajectories at full scale. This reduces iteration cycles and captures tacit surgical knowledge that might otherwise be lost. The third layer involves additive manufacturing and post-processing, requiring precise control of thermal behavior, powder flow, and environmental parameters. SIS integrates IIoT sensor data to maintain real-time digital twins of manufacturing equipment. Inside the Metaverse, engineers monitor build progress and identify potential defects. Early interventions, such as adjusting parameters or modifying support structures, boost reliability and reduce scrap. After printing, essential post-processing steps (heat treatment, machining, polishing, ultrasonic cleaning, and inspection) are scheduled and recorded via SIS to ensure regulatory compliance. The process then continues with sterilization and packaging, critical for clinical safety. Sterilization cycles (autoclave and/or plasma) are carried out under controlled conditions, with temperatures, pressures, exposure times, and biological indicators automatically logged. The Metaverse supports technicians by enabling virtual rehearsals for chamber loading, contamination-risk assessments, and packaging layout optimization. SIS ensures all labeling, UDI codes, and sterile-barrier requirements are documented according to MDR regulations. The final operational stage involves logistics and delivery, aligning with surgical schedules. Personalized implants require precise timing, sterile handling (not always), and controlled environments during transport. SIS tracks real-time geolocation, shock, vibration, humidity, and temperature. If deviations occur, stakeholders are notified immediately. Through the Metaverse, transport teams and hospital staff can simulate routes, rehearse handovers, and coordinate arrival times to match surgery schedules, reducing uncertainty and enhancing operating room preparedness. Throughout all stages, the methodology emphasizes capturing tacit knowledge, the insights of surgeons, engineers, technicians, and logistics personnel. XR interactions and digital twin evaluations naturally record gestures, annotations, and decision sequences. These are transformed into micro-guidelines, or “knowledge atoms,” stored in SIS to support decision-making, training, and quality improvement. Over time, institutions develop an expanding knowledge base that improves consistency and resilience. The methodology was conceptually demonstrated using a personalized Mitković-type internal fixator [12] in pilot SIS environments, selected for its strict anatomical, manufacturing, and sterile-chain requirements. Conceptual analysis of these pilot scenarios indicates that Metaverse collaboration, SIS-integrated workflows, and structured knowledge management can improve speed, quality, and reliability throughout the personalized implant lifecycle. The workflow is defined as a structured data flow linking physical processes with their virtual counterparts (Fig. 1).

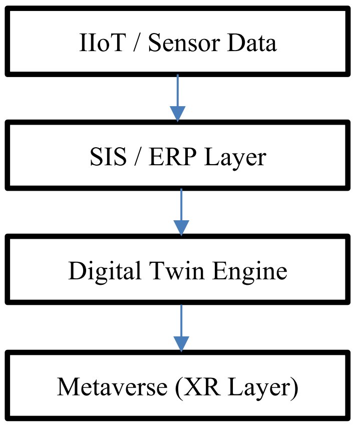

Fig. 1. *The Layers of the System*

IIoT and machine sensor data are first collected from imaging systems, additive manufacturing equipment, sterilization units, and logistics containers. These streams feed into the SIS/ERP layer, which handles authentication, data cleansing, metadata tagging, and regulatory traceability. The cleaned and contextualized data are then sent to the digital twin engine, which maintains real-time virtual models of machines, implants, and logistics assets. The last layer is the Industrial Metaverse (XR environment), where users interact with these digital twins, review process statuses, and collaboratively adjust clinical, engineering, or logistical decisions. Throughout this process, insights generated during XR interactions, known as “knowledge atoms,” are systematically captured and organized in the SIS environment. These structured elements are then stored as reusable decision-support units, allowing institutions to retain expert reasoning, improve training quality, and enhance the consistency of future logistical workflows.

4 MEDICAL PRODUCTION AND LOGISTICS WORKFLOWS

Medical device production and logistics form a closely linked series of activities that must uphold high precision, regulatory standards, and cross-disciplinary collaboration. Personalized implants add extra complexity because each device is unique, urgent, and vital for clinical use. Unlike mass-produced devices, they cannot depend on straightforward workflows or generic distribution methods; instead, they require an integrated, data-rich ecosystem supported by Smart Information Systems (SIS) and Industrial Metaverse technologies. These digital tools revolutionize how clinical diagnostics, engineering design, additive manufacturing, sterilization, packaging, transportation, and surgical prep are coordinated and managed. The workflow begins with clinical diagnostics, where surgeons gather CT, MRI, or X-ray images and transform them into 3D anatomical models. These datasets must be precisely segmented, securely managed, and formatted to be compatible with SIS databases to ensure traceability and interoperability. Since personalized implants are often needed quickly, SIS automates metadata collection, anonymization, and file validation before transferring models into engineering systems. In the Metaverse, surgeons and biomedical engineers can collaboratively examine anatomical structures, annotate fracture details, and predict complications-enhancing communication compared to traditional 2D reviews. The next step involves engineering design and process planning, where detailed implant geometries are developed from anatomical reconstructions. This process balances clinical requirements, such as fixation strength and screw paths, with manufacturing constraints like build orientation, support strategies, and surface finishes. SIS incorporates manufacturability assessments, material data, regulatory standards, and historical case knowledge. Engineers can query previous designs, outcomes, and stored knowledge to inform decisions. Concurrently, the Metaverse enables immersive design reviews where surgeons can manipulate virtual implants at full scale and simulate placement on the patient’s anatomy. These interactions reduce the number of iterations and help identify potential design issues early. Once the design is approved, the process advances to additive manufacturing (AM). Techniques like selective laser melting (SLM) require precise control over thermal behavior, powder flow, and environmental conditions. SIS can collect real-time machine data and generate digital twins that monitor energy input, thermal gradients, and deformation risks. Inside the Metaverse, supervisors visualize the build in an immersive environment, highlighting overheating, layer defects, or distortion zones. Deviations can be corrected swiftly, with the updated digital twin maintaining synchronization. After printing, post-processing steps-such as powder removal, heat treatment, machining, polishing, and inspection, are scheduled through SIS to ensure accuracy and compliance. XR visualization helps technicians practice machining or finishing tasks and compare expected outcomes with actual results. The workflow then proceeds to sterilization, packaging, and traceability. Sterilization cycles must be thoroughly logged in SIS, including temperature, pressure, and biological indicators. Packaging must preserve sterility and include accurate labeling in accordance with MDR and UDI regulations. The Metaverse supports these processes by allowing technicians to simulate chamber loading, identify contamination risks, and optimize packaging layouts before physical implementation. Finally, hospital logistics and surgical coordination demand precise timing and environmental management. Personalized implants need to arrive in the operating room within strict timeframes. SIS coordinates transport schedules, monitors temperature and shocks, and provides real-time tracking. Any deviations trigger alerts. The Metaverse offers an immersive environment where hospital staff, transport teams, and surgical crews rehearse handovers and synchronize deliveries to meet surgical schedules. Overall, integrating SIS with the Industrial Metaverse transforms medical production and logistics into a connected, digital-first ecosystem. These technologies improve traceability, communication, decision-making, and safety across the entire lifecycle of personalized implants, which are becoming increasingly vital in modern healthcare medicine.

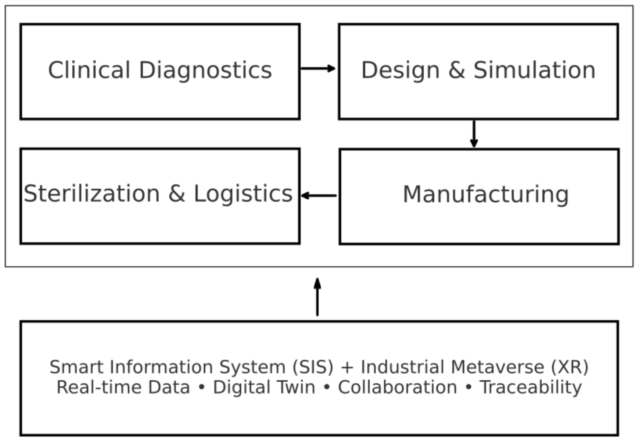

Fig 2. *Simplified Workflow System*

5 METAVERSE INTEGRATION IN MEDICAL PRODUCTION AND LOGISTICS

Medical device production and logistics are closely linked processes that must maintain precision, regulatory compliance, and cross-institutional coordination. The complexity increases significantly for personalized implants, which require rapid decision-making, strict timing, and sterile chain integrity throughout their lifecycle. Smart Information

Systems (SIS) supports the initial phase by automating metadata collection, ensuring traceability, and transferring validated anatomical models into design platforms. This creates a unified data foundation that prevents delays and errors during early implant preparation stages. Engineering design and process planning combine clinical requirements with manufacturability constraints. In this stage, SIS aggregates material data, previous case knowledge, and regulatory standards, while Industrial Metaverse tools provide an intuitive environment for interdisciplinary design reviews. Immersive visualization in the Metaverse helps engineers quickly identify deviations and predict defects, which is critical when operating under urgent clinical timelines. SIS coordinates post-processing operations, including heat treatment, machining, finishing, and quality inspection, to ensure compliance with medical device standards. Sterilization, packaging, and documentation follow as key safety steps. Each sterilization cycle must be recorded with precise parameters (temperature, pressure, exposure time), while SIS manage UDI labeling, MDR compliance, and the integrity of sterile barriers. XR simulations help technicians optimize chamber loading patterns or spot contamination risks before performing actual procedures. Hospital logistics conclude the workflow and often determine whether an implant arrives in time for surgery. Personalized implants require controlled environments, reliable routing, and synchronization with surgical schedules. SIS provides real-time tracking of location, temperature, humidity, vibration, and shock, and sends immediate alerts when deviations occur. Within the Metaverse, logistics operators and hospital staff can rehearse handover procedures, evaluate risk scenarios, and coordinate arrival times to ensure sterile chain continuity and operating room readiness. Overall, integrating SIS and Industrial Metaverse technologies transforms medical production and logistics into a coordinated digital ecosystem. The potential integration of the Metaverse in medical manufacturing and logistics is illustrated in Fig. 3.

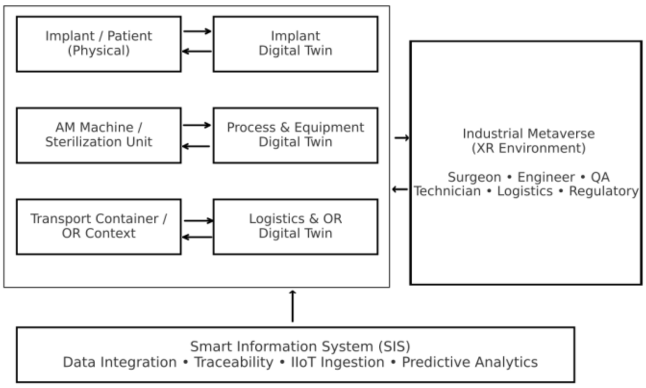

Fig. 3. *Metaverse integration into manufacturing and logistics*

Rather than functioning as isolated departments, clinical, engineering, manufacturing, sterilization, and logistics teams operate on shared data and immersive process visibility—improving reliability, reducing uncertainty, and supporting the timely delivery of personalized implants. This tightly connected workflow ensures that every decision, from design refinement to final sterile release, is informed by real-time information and collective situational awareness.

6 TACIT KNOWLEDGE IMPLEMENTATION

Tacit knowledge is the informal, experience-based expertise that clinicians, engineers, technicians, and logistics specialists develop through practice. It is expressed through perception, spatial reasoning, intuitive pattern recognition, and subtle judgment. This type of knowledge guides decisions such as how surgeons adjust screw placement, how engineers identify early signs of build instability, how sterilization technicians recognize contamination risks, and how logistics operators interpret environmental conditions during transport. These insights are essential for safety and reliability, especially when producing unique, patient-specific implants. Capturing tacit knowledge is challenging because conventional digital systems primarily record explicit parameters such as machine settings, timestamps, and inspection reports, while overlooking subtle human decisions during real processes. The Industrial Metaverse, combined with Smart Information Systems (SIS) and digital twins, makes expert reasoning observable, recordable, and reusable through immersive interaction. In clinical settings, surgeons rely heavily on tacit judgment when examining anatomy and choosing fixation strategies. Within XR environments, they can manipulate patient-specific models, evaluate implant fit, and test screw trajectories. Their movements, spoken observations, and adjustments are automatically recorded. Once encoded in SIS, this information becomes structured micro-knowledge that supports future design, enhances training, and preserves expertise even when staff change. Engineers also rely on tacit knowledge when interpreting sensor data or detecting early signs of additive manufacturing defects, such as melt pool irregularities or unusual powder distribution. In Metaverse environments, engineers can interact with machine digital twins, annotate potential risk areas, and demonstrate diagnostic reasoning. Recorded interactions enable younger staff to learn expert decision-making without a lengthy apprenticeship. Post-processing steps such as machining, polishing, and cleaning require skilled handling. XR simulations allow technicians to practice these tasks, producing motion paths and handling patterns that can be stored in SIS as standardized work sequences. Sterilization and cleanroom logistics similarly depend on human intuition. Virtual chambers enable technicians to visualize airflow, risk zones, and layout options while capturing their adjustments as reusable knowledge. Logistics operations also contain key tacit expertise. Experienced staff understand which transport routes cause excessive vibration, how environmental conditions affect sterile packaging, and how timing impacts operating room readiness. Metaverse-based rehearsals enable virtual testing routes and the annotation of potential risks, creating guidance that can be shared across organizations. Transforming tacit knowledge into structured micro-knowledge improves institutional performance by reducing variability through consistent expert guidance. It enhances training by enabling personnel to replay and study expert reasoning. It strengthens compliance by making human decision logic more transparent. Finally, it improves interdisciplinary communication by making implicit expertise visible across clinical, engineering, manufacturing, sterilization, and logistics domains. Integrating tacit knowledge into SIS and Metaverse workflows creates a more predictable, resilient, and human-centered system for personalized implant production.

7 CONCLUSION

The increasing demand for personalized medical devices has exposed significant flaws in traditional production and logistics systems designed for mass manufacturing, leading to extended delivery timelines. Modern healthcare now requires highly flexible workflows capable of managing unique anatomical shapes, urgent clinical schedules, and strict sterile-chain protocols. This paper presents a concept for an integrated framework in which Smart Information Systems (SIS) and Industrial Metaverse technologies collaborate to address the complexity of producing and distributing personalized medical devices. SIS serves as the digital backbone of this ecosystem by facilitating IIoT connectivity, real-time monitoring, workflow automation, and regulatory traceability. They ensure that clinical imaging data flows securely into engineering environments, that manufacturing processes are continuously monitored, that sterilization cycles are accurately documented, and that logistics conditions remain transparent and predictable. Digital twins enhance these capabilities by replicating machines, implants, sterilization units, and transport containers, forming a unified, constantly updated information layer throughout the implant's lifecycle. The Industrial Metaverse adds a dynamic experiential element through immersive, multi-user collaboration. Surgeons and engineers can examine implant geometries and patient anatomy at full scale, manufacturing teams can visualize potential process deviations, and sterilization technicians can rehearse loading patterns or contamination scenarios virtually. Logistics teams can simulate transport routes and environmental risks before making real-world decisions. These interactions help eliminate communication gaps between clinical, engineering, production, and logistics teams, which historically lead to errors or delays. A key contribution of this framework is its ability to capture tacit knowledge-such as surgical intuition, engineering judgment, sterile-handling expertise, and logistics insights. Through XR interactions and digital twin observation, these forms of knowledge can be converted into reusable micro-knowledge units embedded within SIS for training, decision support, and quality improvement. Ultimately, the proposed framework outlines a pathway toward faster, safer, and more reliable delivery of personalized medical devices across the entire chain.

ACKNOWLEDGMENT

This research was supported by the ERASMUS+ Project "Extended Reality for Machine Tool Training" - XMAN (Project Reference: 2023-1-PL01-KA220-VET-00162134), which aims to improve vocational education and training in manufacturing by integrating extended reality (XR) technologies into machine tool operation training.

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Contact address:
Nikola Vitković
University of Niš
Faculty of Mechanical engineering
18000 Niš
A. Medvedeva 14
E-mail: nikola.vitkovic@masfak.ni.ac.rs