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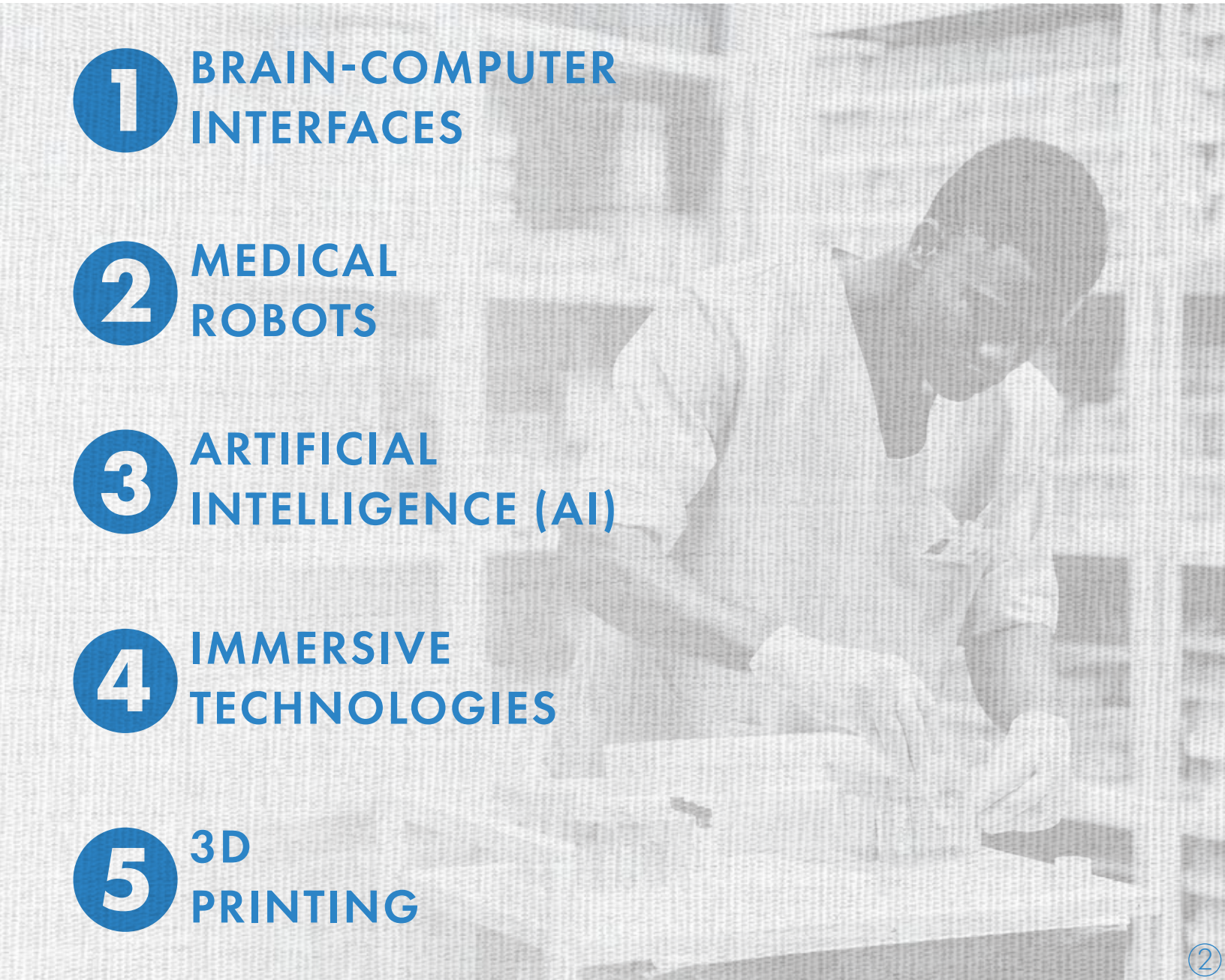
2025 MEDICAL DEVICE INDUSTRY TRENDS

As we move into 2025, the medical device industry continues to push the boundaries of innovation. Patients and healthcare providers alike are driving demand for smarter, more precise, and highly integrated technologies that enhance both treatment and patient experience.

In the coming year, we expect to see groundbreaking advancements in brain-computer interfaces, which are now entering early-stage human trials, as well as significant progress in robotics, expanding the capabilities of robot-assisted laparoscopic surgeries. Artificial intelligence (AI) and machine learning (ML) will play an even greater role in medical device software, while immersive technologies like virtual and augmented reality will reshape medical training and patient care. Additionally, 3D printing is making strides in personalized medicine, allowing for the creation of customized implants and prosthetics.

This report explores these five key trends that will shape the medical device industry in 2025 and beyond.



1 BRAIN-COMPUTER INTERFACES

Brain-computer interface (BCI) technology has been making more noise over the past year, as early clinical studies of invasive interfaces have generated positive press and more is to come in 2025. BCI technology helps direct communication between the brain and external devices. Artificial Intelligence (AI) is often embedded in these medical devices.

In 2025, BCI technology is expected to advance in many ways, including increased use for assistive technologies, treatment of neurological disorders, neuro-prosthetics, cognitive training, and neurorehabilitation.

Neurological disorders like Parkinson's disease, Alzheimer's, epilepsy, and spinal cord injuries may be improved using BCI technology. AI-driven BCIs can help patients with locked-in syndrome and neurodegenerative diseases regain mobility and communication.

BCI neuro-prosthetic devices are helping paralyzed individuals regain movement via brain-controlled wheelchairs, robotic limbs, and speech assistance devices. BCI-powered exoskeletons and robotic prosthetics are giving hope to patients with severe motor disabilities, allowing them to regain movement with the power of thought.

BCIs also help in cognitive rehabilitation and neurorehabilitation, allowing patients to recover from debilitating conditions such as stroke or traumatic brain injuries. Researchers are developing personalized solutions that use BCIs to monitor brain activity in real time and adjust rehabilitation exercises accordingly. This customized approach helps patients recover motor functions faster, improving their quality of life.

There are market challenges with BCIs such as prohibitive cost, limited access, complex regulatory hurdles, technical issues, and ethical

2 MEDICAL ROBOTS

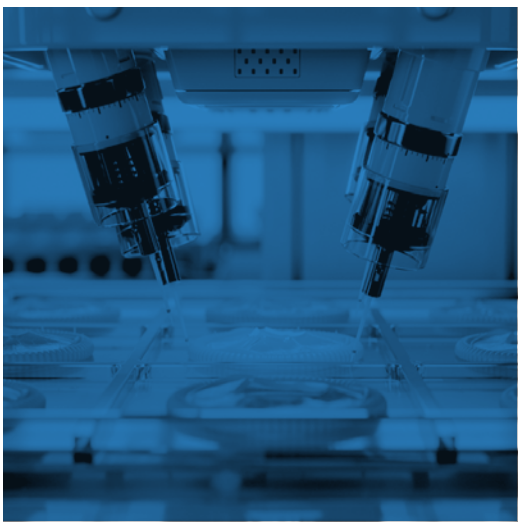
Robotics will enhance precision in surgeries and rehabilitation, improving patient outcomes for more people with increased competition entering the market in 2025. Medical robot-assisted surgery has been slowly replacing conventional surgical methods for the past 25 years with the Intuitive Surgical da Vinci robot owning the market. Robots are now routinely used in many laparoscopic soft tissue procedures, including cardiac, urologic, gynecologic, and general surgery for better targeting and patient safety. These surgeries ensure that patients undergo smaller incisions, less blood loss, and recover faster while the surgeons receive help from improved ergonomics and dexterity in comparison to traditional laparoscopy.

Now, dozens of newcomers are pursuing niche applications of robotics in surgery. Medtronic is in a strong second place with their Hugo robot. Other players include Johnson & Johnson, CMR Surgical, Distalmotion, Virtual Incision, Moon Surgical, Medical Microinstruments, Procept Biorobotics, Stryker, and Zimmer Biomet. MEDTECHDIVE reported that 10 years from now, Intuitive is expected to have 70% of the market with Medtronic and Johnson & Johnson each having 10%. All other firms will account for the remaining 10% market share.

There are also many applications for medical robotics outside the surgical suite. We will discuss two examples:

First is RIF Robotics, who created a robotic system that automates surgical tray preparation. This system uses computer vision and robotics to identify, inspect, and handle surgical instruments.

Second is BioBOTs by Theranautilus, which are specialized magnetic nanobots laced with bioactive components used to permanently treat hypersensitivity and promote tooth regeneration.



According to a report by Mordor Intelligence, the Medical Robotic Systems Market size is expected to reach $28.14 billion by 2029, growing at a CAGR of 16.13% during the forecast period (2024-2029).

3 ARTIFICIAL INTELLIGENCE (AI)

Artificial Intelligence (AI) will assist in diagnostics, predictive analytics, and personalized treatment plans in 2025. It is increasingly being integrated into medical devices, transforming healthcare by improving diagnosis, treatment, and patient care. A Nature.com article states that 950 medical devices driven by AI/ML have been approved by the U.S. Food and Drug Administration (FDA) for potential use in clinical settings.

In response, the FDA has recently increased the pace of issuing guidance related to medical devices embedded with AI and ML.

The most significant applications of AI in medical devices include diagnosis, prognosis, treatment planning, and monitoring:

- AI algorithms analyze medical images and patient data, including genetic information, to detect diseases with high accuracy and speed
- AI predicts disease progression and treatment outcomes, thereby enabling personalized care and early intervention
- AI assists surgeons in planning complex procedures by analyzing patient data and generating 3D models
- AI-enabled sensors can track vital signs, detect anomalies, and provide real-time feedback to healthcare professionals

Medical device manufacturers are also integrating AI technologies like computer vision to enhance robotic surgery. AI also finds application in automating and optimizing medical device production workflows thereby reducing device cost.

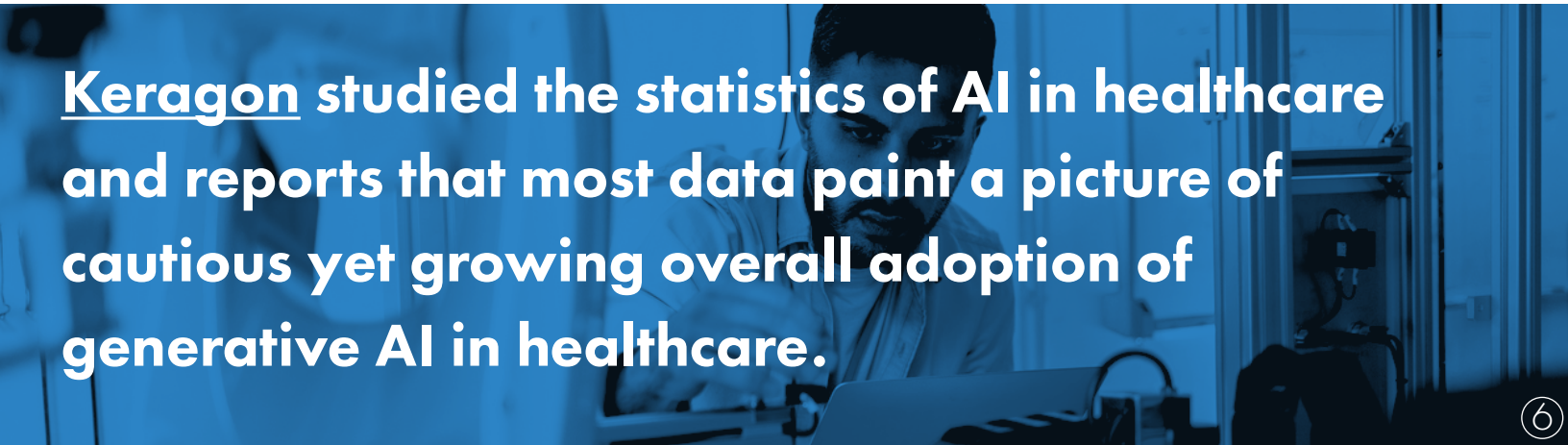
There are also challenges and considerations for AI in medical devices, which are addressed in the FDA guidance documents:

- **Data quality and bias:** AI algorithms are only as good as the data they are trained on; as such, ensuring high-quality, unbiased data is crucial.
- **Regulation and safety:** AI-enabled medical devices must meet rigorous regulatory standards to ensure patient safety.
- **Transparency and interpretability:** AI algorithms must be understandable and explainable to healthcare professionals and patients.
- **Ethical considerations:** AI in healthcare raises ethical concerns related to privacy, data security, and decision-making.

A few examples of AI/ML in medical devices include:

- Medtronic has obtained European CE Mark and U.S. FDA approval for the world's first adaptive deep brain stimulation (aDBS) system for people with Parkinson's disease. Medtronic enhanced its Percept™ DBS neurostimulators with exclusive BrainSense™ Adaptive technology, which provides enhanced therapy personalization for symptom control that automatically adjusts, minimizing the need for patients to manually adjust stimulation. The U.S. FDA approval also includes Medtronic's BrainSense™ Electrode Identifier (EI), which helps reduce the time required to program the patient's aDBS settings. Medtronic claims that clinicians can conduct accurate and precise initial programming 85% faster by using EI compared to traditional electrode selection.
- Nightingale's HEARThermo has developed an AI-enabled monitoring device that allows healthcare providers to predict infections during an infectious outbreak.
- PneumoWave's chest-worn biosensor captures respiratory data that is analyzed using ML algorithms to detect early signs of deterioration and notifies the patients and physicians.

According to Dartmouth Health, the market for AI in healthcare is expected to grow to more than $45 billion in 2026.



4 IMMERSIVE TECHNOLOGIES

Virtual reality (VR), augmented reality (AR), and extended reality (XR) will be increasingly used for medical training, patient education, surgical procedures, and medical device manufacturing in 2025.

Standard medical device images and videos are static. Immersive technologies overcome this limitation to provide a first-person perspective that creates a sense of presence. This can improve patient care, provide greater surgical precision, and enhance training of health care professionals and patients.

AR and VR are transforming the medical device industry in a number of ways. Surgeons leverage AR for real-time 3D visualizations during procedures, while medical students and professionals use it for anatomy training and surgical overlays. AR also improves patient interactions through symptom checker chatbots that provide instant feedback. Meanwhile, VR is revolutionizing medical training by allowing professionals to practice complex procedures in a risk-free environment and is increasingly used in therapy for mental health treatment and pain management.

Some firms are using VR, AR, and XR in medical device manufacturing to improve product design and reduce manufacturing costs. These technologies improve the patient's quality-of-care, improve rehabilitation, and enhance engagement. For physicians, immersive technologies provide better decision support.

A good example of AR innovation is Precision OS that uses AR and VR to offer orthopedic surgeons immersive training experiences. Their platform enables surgeons to practice procedures in a realistic virtual environment, improving confidence and technical skills. CleverPoint offers hardware that uses VR-integrated wearables to decode brain processes. Its product, CleverPoint, captures and assesses patient reactions to VR content through neurofeedback. It gathers biofeedback for professionals to analyze patient responses to virtual environments to advance the understanding and management of brain processes.

ViRe Instruments offers a VR headset and a platform that allows doctors to easily load and view DICOM files in 3D from new perspectives, which is not possible with traditional views. Specialized modules are available for areas like vascular surgery and oncology. An ultrasound module is available to view pre-natal images in VR or share with family in AR/VR.

Gartner predicts that, "*By 2027, 70% of the top ten Fortune 500 companies will have implemented an augmented connected worker initiative. Furthermore, by 2028, 45% of organizations with more than 500 employees will use employee AI avatars to expand the capacity of human capital.*"

5 3D PRINTING

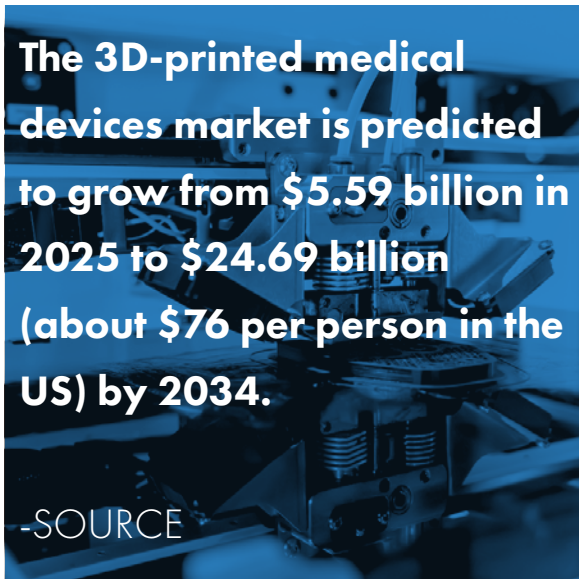
Customized implants and prosthetics allowing for patient-specific treatments will become more common in 2025. 3D printing has advanced from prototyping and small replacement part manufacturing to show potential in creating custom prosthetics and implants. The sector is expected to continue to grow as more healthcare practitioners embrace the technology. In 2025, this technology is expected to include printing of human tissues and organs – the ultimate in patient-specific treatments.

3D printing will be used to create personally tailored medical devices such as hearing aids, dental implants, and orthopedic implants, which will enhance comfort, fit, and outcomes while lowering the risk of complications.

Surgical guides that precisely fit a patient's anatomy are made using 3D printing and increase success rates of spinal replacements and other complicated surgeries. This lessens the possibility of issues and protracted hospital stays.

3D printing or additive manufacturing offers an opportunity to better integrate anatomical and pathological structures in the design of medical devices, which enhances the fit of implants to body parts. Additive manufacturing also presents better scaffolds for pre-surgical planning and training.

The 3D-printed medical devices market is predicted to grow from $5.59 billion in 2025 to $24.69 billion (about $76 per person in the US) by 2034. This growth is attributable to rising demand for customized 3D printed solutions – something we will continue to see moving into 2025 and beyond



LOOKING AHEAD

These medical device trends highlight the ongoing innovation and technological advancements in the medical device industry. Wearable technology, minimally invasive diagnostics, brain-computer interface, robotics, embedded AI, immersive technologies, and 3D printing all aim to improve patient care and outcomes. They all will continue to grow and have the potential to transform the medical device sector.

Given our deep industry knowledge and consulting services experience, Clarkston Consulting is well-suited to help businesses successfully navigate the changes associated with these trends – whether it is integrating point-of-care technologies, streamlining supply chains for the unique challenges these medical devices pose, using AI in medical devices, or any of the other trends. Reach out to our team to learn more about how these advancements are influencing healthcare in the future and how we can work with you to stay ahead of the curve in the ever-evolving medical device market.

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