

PRESS RELEASE April 22, 2025

Pixee Medical Receives FDA 510(k) Clearance for Augmented Reality solution tailored to U.S. **Ambulatory Surgery Centers**

22 April 2025 - Besançon, France. *Pixee Medical, a pioneer in Augmented Reality* (AR) navigation for orthopedic surgery, announces FDA 510(k) clearance of Knee⁺ NexSight, the cutting-edge AR guidance solution for total knee arthroplasty. This next-generation of AR was designed to address the fast-growing market of ambulatory surgical centers (ASCs).

Knee⁺ NexSight represents the next evolution in Augmented Reality for the OR. Developed with insights and feedback from orthopedic surgeons and built on top of a platform with more than 10,000 successful procedures performed worldwide, it addresses the unique demands of the high-efficiency and cost-sensitive U.S. surgical environments.

"Knee⁺ NexSight is not just an evolution of our clinically proven technology, it's a new approach built around the realities of U.S. outpatient care, informed by the expertise of U.S. surgeons and a proven worldwide track record of our earlier solutions", explained Sébastien Henry, founder and CEO of Pixee Medical.

Robotic-like precision¹, without the complexity or cost

Knee⁺ NexSight is engineered to deliver accuracy and reliability associated with robotic-like precision, but in a streamlined, accessible format. Surgeons benefit from advanced wearable guidance that enhances intraoperative decision-making and reproducibility, without the need for bulky robotic systems or significant capital investment.

"Knee⁺ NexSight allows surgeons to position knee implants with remarkable precision, according to the exact specifications they determine for each patient. This augmented reality technology eliminates the need for costly preoperative imaging while ensuring placement precision to the degree. Compatible with all existing implant systems, Knee⁺ NexSight integrates naturally into surgeons' usual procedures, minimizing the learning curve. This innovative solution improves total knee arthroplasty outcomes while offering simple and efficient technology adoption", said Dr. Scott R. Nodzo, Orthopedic Surgeon - Buffalo, NY





Purpose-Built for the U.S. ASC market

With the U.S. ASC market projected to exceed \$75 billion by 2030, Knee⁺ NexSight offers a compact, cost-effective, and sustainable solution that eliminates physical disposables and minimizes environmental impact. Fully compatible with all primary total knee implants, it integrates effortlessly into diverse surgical settings, from highvolume outpatient centers to hospital-based practices.

First-ever enhanced connectivity for future-ready surgery

Knee⁺ NexSight introduces a optional connectivity module that enables secure data exchange with third-party web solutions. This forward-thinking feature unlocks the full potential of the system through secure data sharing capabilities and seamless software updates, positioning surgical teams for enhanced workflow integration and future technological advancements in orthopedic care.

About Pixee Medical

Pixee Medical develops augmented reality solutions for implant placement that offer orthopedic surgeons cutting-edge and clinically proven tools for precise and efficient surgery. Its first product has already been used in over 10,000 procedures in more than 20 countries, demonstrating its positive impact on surgical practices worldwide.

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¹ Lambrechts J, Vansintjan P, Lapierre C, Sinnaeve F, Van Lysebettens W, Van Overschelde. Accuracy of a New Augmented Reality Assisted Technique for Total Knee Arthroplasty: An In Vivo Study. Arthroplast Today. 2024.

