Chapter 16
Ethical and Regulatory Evaluation of Autonomous AI Systems in Surgical Practices

S. Ida Evangeline
https://orcid.org/0000-0003-2997-7897
Government College of Engineering, Tirunelveli, India

ABSTRACT

Autonomous artificial intelligence (AI) systems are transforming surgical practice, enabling enhanced precision, efficiency, and personalization. Yet, their integration introduces critical ethical and regulatory challenges. This chapter explores current applications of AI in surgical settings—preoperative planning, intraoperative decision-making, and postoperative monitoring—highlighting clinical benefits alongside risks such as algorithmic bias and lack of explainability. Key ethical issues are examined, including informed consent, moral responsibility, and data privacy. The chapter also evaluates global regulatory responses, such as the FDA's Total Product Lifecycle model and the EU's Artificial Intelligence Act. Case studies, including the da Vinci Surgical System and the Smart Tissue Autonomous Robot, illustrate real-world implications. The chapter concludes with forward-looking recommendations emphasizing adaptive regulation, interdisciplinary collaboration, and human-centered design to responsibly guide AI's role in surgical care.

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INTRODUCTION

The rapid advancement of artificial intelligence technologies is revolutionizing the landscape of modern medicine, particularly in surgical practices. Autonomous AI systems are increasingly being integrated into the surgical workflow—augmenting human decision-making, enhancing precision, and enabling minimally invasive procedures that were once considered unattainable. Robotic assisted operations, AI enabled diagnostic imaging and intraoperative guidance are among the technologies that hold the promise of a paradigm change in the way surgical care is rendered offering a potential to improve patient outcome, decrease the surgical errors, and increase the efficiency of the healthcare systems (Guni et al., 2024).

However, the integration of autonomous AI into surgical environments does not come without profound ethical and regulatory challenges. Surgical decision-making is a high-stakes endeavor, often involving life-or-death consequences, where the application of AI must be approached with extreme caution. There are urgent ethical questions around patient safety, liability attribution, informed consent, algorithmic bias, and transparency (Muniasamy et al. 2026; Gauthaman, S. A., et al. 2026; Gauthaman et al., 2026). In the case where AI systems make mistakes in their decisions who is at fault? When patients cannot understand non-human agents' decision processes, can they really consent to procedures guided by such agents? What safeguards are needed in order for these technologies to not perpetuate or worsen already existing disparities, or introduce new risks? (Morris et al. 2024)

Moreover, the regulatory ecosystem has struggled to keep pace with the accelerating development of surgical AI technologies. Traditional frameworks for medical device approval and oversight are often ill-suited to address the adaptive and opaque nature of machine learning algorithms (Muniasamy et al. 2026; Gauthaman, S. A., et al. 2026; Gauthaman et al., 2026). However, with continuous learning after deployment, the need for dynamic and proactive regulatory mechanisms increases. While a patchwork of guidelines—regulatory approach by the U.S. Food and Drug Administration (FDA) to the European Union's (EU) Artificial Intelligence Act—is emerging, there is no cohesive and globally harmonized framework (Iftikhar et al. 2024).

This chapter provides a structured and critical examination of the ethical and regulatory dimensions associated with the deployment of autonomous AI systems in surgical settings. The discussion will begin by mapping the current capabilities and applications of AI in surgical practice, followed by an exploration of the core ethical dilemmas that arise from its use. Then, it will discuss explainability and why interpretable AI models are needed in clinical settings. We will present a detailed analysis of the global regulatory landscape, including policy gaps, liability concerns, and emerging legal precedents. We will then discuss the promise and peril of au-