### **Review Article**

DOI: https://dx.doi.org/10.18203/2349-2902.isj20252705

# Intraoperative stapler misfire in gastrointestinal surgery: recognition, management, and prevention

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Received: 29 June 2025 Accepted: 05 August 2025

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#### **ABSTRACT**

Surgical staplers have revolutionized gastrointestinal surgery, offering precision, speed, and reduced blood loss. Yet, stapler misfires remain an under-recognized intraoperative hazard with the potential to cause devastating complications, including anastomotic leak, haemorrhage, and reoperation. Despite their clinical significance, these events are often underreported, inconsistently managed, and poorly understood by surgical teams. This review aims to provide a comprehensive overview of intraoperative stapler misfire in GI surgery. It covers etiopathogenesis, classification, clinical recognition, intraoperative salvage strategies, prevention through training and technology, and insights from contemporary randomized controlled trials and global device surveillance. A literature review was conducted using PubMed, Cochrane Library, and FDA databases for studies published between 2015 and 2025. Only peer-reviewed articles, systematic reviews, RCTs, and major adverse event reports related to GI stapling devices were included. Intraoperative stapler misfires result from a complex interplay of device mechanics, tissue characteristics, user technique, and environmental constraints. Powered staplers and smart sensing systems have reduced some risks, but human judgment and intraoperative vigilance remain the cornerstone of safety. Evidence suggests that misfires occur in up to 1.5% of GI stapler uses, with a significant proportion requiring conversion to hand-sewn techniques or leading to re-intervention. Surgeons must be equipped not only to operate advanced stapling devices but also to recognize and manage their failures promptly. Structured intraoperative algorithms, informed device selection, pre-emptive leak testing, and documentation are essential. This review provides the foundation for standardizing the surgical response to stapler misfires and advocates for transparency, training, and innovation in surgical safety.

**Keywords:** Stapler misfire, Gastrointestinal surgery, Device malfunction, Powered staplers, Surgical safety, Simulation training, Medicolegal risk, Systematic review, Randomized trials, Innovation

### INTRODUCTION

Surgical stapling has transformed the landscape of gastrointestinal (GI) surgery, enabling faster anastomoses, improved hemostasis, and reproducible outcomes. From minimally invasive colectomies to bariatric reconstructions and pancreatic resections, staplers have become integral to modern operative workflows. Despite this widespread adoption, stapler misfires - mechanical malfunctions or tissue-related failures resulting in incomplete staple formation, bleeding, or tissue disruption - remain a potentially catastrophic and underreported complication of GI surgery.

The true incidence of intraoperative stapler malfunction is difficult to quantify, largely due to variability in device reporting, institutional documentation practices, and under recognition of subtle misfire events. Nevertheless, recent FDA reports, retrospective audits, and multicentre surveys suggest that stapler-related adverse events occur in up to 1.5% of GI procedures, with nearly half necessitating an intraoperative repair or deviation from the planned anastomotic technique. Powered stapling systems, precompression algorithms, and reload tracking have offered some mitigation, but these advances are not immune to failure - particularly in anatomically restricted or inflamed operative fields.

The implications of a stapler misfire extend far beyond the immediate surgical event. Delayed recognition may culminate in anastomotic dehiscence, abscess formation, prolonged hospitalization, or even mortality. Additionally, device-related failures often trigger medicolegal scrutiny and institutional reporting obligations, compounding the stress of surgical error with administrative and legal consequences.<sup>4</sup> Given this burden, it is imperative for surgeons to possess a high index of suspicion, a robust armamentarium of intraoperative troubleshooting strategies, and an intimate familiarity with the mechanical behaviour of stapling systems.

This review seeks to define the scope of stapler misfire in GI surgery through an integrated lens of clinical experience and evidence-based literature. We explore underlying mechanisms, classification systems, intraoperative warning signs, and management protocols, while incorporating recent randomized trials and device safety communications. Furthermore, we emphasize the importance of training, documentation, and ethical disclosure in navigating the grey zones of surgical technology failure.

### EPIDEMIOLOGY AND INCIDENCE

Stapler misfire in gastrointestinal surgery is increasingly acknowledged as a relevant cause of intraoperative deviation, morbidity, and postoperative complications. While exact prevalence remains elusive due to underreporting and inconsistent definitions across studies, available data suggest that misfires and related device malfunctions may occur in 0.3% to 1.5% of GI surgical stapler uses across various procedures. These figures likely represent underestimates, particularly given the lack of standardized adverse event classification and the reluctance among surgical teams to formally document device-related errors.

A multicentre retrospective analysis from Japan examining over 14,000 gastrointestinal resections reported an overall stapler malfunction rate of 0.78%, with colorectal and esophagogastric surgeries demonstrating the highest incidence. Similarly, a comprehensive evaluation of bariatric surgery stapling complications across 112 centres identified a misfire-related leak rate of 0.6%, often culminating in re-intervention. These complications are disproportionately represented in procedures involving dense, edematous, or inflamed tissue - such as inflammatory bowel disease resections or redo surgeries where device-tissue mismatch is common.

The US FDA's Manufacturer and User Facility Device Experience (MAUDE) database, though not systematically validated, remains a crucial repository for post-market surveillance of stapler safety. Between 2015 and 2021, over 50,000 adverse event reports involving surgical staplers were recorded, with approximately 4,000 incidents classified as serious - ranging from bleeding and leak to organ perforation and death. <sup>11</sup> Notably, the

majority of these reports implicated reload failures, improper tissue compression, or component jamming, often in the context of laparoscopic surgery where visual cues are prioritized over tactile feedback.

Despite growing awareness, reporting remains inconsistent across institutions and countries. A survey conducted among European colorectal surgeons revealed that fewer than 30% routinely document intraoperative stapler malfunction unless it led to postoperative complications. <sup>12</sup> This cultural underreporting not only hinders quality improvement but also impedes broader efforts toward evidence-based device refinement and regulatory oversight.

# MECHANISMS AND TYPES OF STAPLER MISFIRE

Stapler misfire is not a singular technical event but rather a constellation of mechanical, procedural, and biological failures that culminate in suboptimal staple formation or tissue division. A comprehensive understanding of these failure modes is essential to ensure timely intraoperative recognition and safe surgical salvage.

### Classification of misfire types

Stapler misfires may be categorized based on the functional defect observed during deployment.

Failure to fire

The device trigger is activated but no staples are deployed, often due to internal mechanical obstruction, misalignment of the anvil and cartridge, or actuator system failure.<sup>13</sup>

Incomplete staple formation

Staples are ejected but do not achieve their intended "B" configuration, leading to poor tissue approximation and a high risk of bleeding or anastomotic leak.<sup>14</sup>

Tissue crush or tear

Inappropriate cartridge selection for thick, fibrotic, or edematous tissue may cause tearing, crushing, or slippage between the jaws.<sup>15</sup>

### Misalignment of stapler

Poor visualization, awkward angles, or hasty positioning may lead to off-axis closure, resulting in asymmetric staple lines or unintended tissue incorporation. <sup>16</sup>

Jammed reloads or cartridge misfit

Stapler reloads may fail to seat properly within the device, resulting in locked firing mechanisms or partial deployment.<sup>17</sup>

#### Underlying mechanisms

The mechanical integrity of a stapler depends on the synchronized interaction between its components—cartridge, anvil, shaft mechanics, and firing system. Failures can result from manufacturing defects, improper device assembly, or deviation from standard firing protocols. For instance, over-tightening or early release during precompression can interfere with staple formation and tissue sealing. Moreover, powered staplers—though designed to minimize human variability—can also misfire due to incomplete battery charge, excessive tissue resistance, or software latency in smart firing systems.

Operator error remains a major contributor. Failure to wait the recommended duration for tissue compression, ignorance of cartridge-tissue mismatch thresholds, and rushing the reload process are frequent pitfalls. Environmental constraints—such as narrow pelvic anatomy, limited laparoscopic working space, or active bleeding obscuring the staple line—further increase the risk of technical compromise.

# CLINICAL RECOGNITION OF STAPLER MISFIRE

The timely recognition of a stapler misfire is critical to minimizing intraoperative harm and preventing downstream complications such as hemorrhage, anastomotic leak, or sepsis. While some misfires are obvious—manifesting as a locked device or gross staple line defect—others are subtler, particularly in laparoscopic or robotic environments where tactile feedback is limited.

#### Intraoperative indicators

Surgeons must maintain a high index of suspicion during any stapled anastomosis, especially in high-risk anatomical zones or when using newer devices. The most common visual cue is an irregular or incomplete staple line, characterized by gapping, missing staples, or tissue protrusion. Brisk bleeding at the staple line should raise immediate concern for incomplete closure or vessel injury, often necessitating prompt hemostasis and inspection.<sup>19</sup>

Unexpected resistance during firing is another hallmark—suggesting jammed reloads, thickened tissue, or mechanical dysfunction. In powered devices, delayed or failed actuation may indicate low battery or software interruption. Tactile feedback, though diminished in laparoscopy, can still offer clues when a stapler feels unusually stiff, loose, or fails to lock.<sup>20</sup>

### Postoperative manifestations

Intraoperative misfires that go unrecognized may present postoperatively as anastomotic leaks, most commonly between postoperative days 3–7. These manifest as fever, leukocytosis, peritonitis, or increased drain output.

Delayed hemorrhage or intra-abdominal sepsis may also result from poorly formed staple lines.<sup>21,22</sup>

In bariatric or rectal resections, where staple lines are long and sometimes multi-cartridge, small imperfections can snowball into major complications if not inspected thoroughly. Subclinical leaks may only be detected through early postoperative imaging or escalating clinical signs.

#### Diagnostic adjuncts

Adjunctive testing during surgery plays a key role in misfire recognition. Air-leak tests and methylene blue dye insufflation are simple yet effective methods to check staple line integrity in colorectal and gastric anastomoses. In bariatric and sleeve surgeries, these techniques can detect subtle mucosal defects or staple gaps before closure.<sup>23</sup>

Intraoperative endoscopy is especially valuable in difficult pelvic dissections or high-risk patients. It enables direct visual confirmation of mucosal integrity, staple alignment, and bleeding control—potentially avoiding reoperation.<sup>24</sup>

#### INTRAOPERATIVE STRATEGIES

**MANAGEMENT** 

When a stapler misfire is identified intraoperatively, the surgeon's response must be immediate, systematic, and focused on minimizing harm. The consequences of delay—ranging from persistent bleeding to anastomotic failure—can escalate rapidly if corrective action is not timely and well-structured. A pragmatic, algorithmic approach is essential.

#### Immediate response protocol

The first priority is patient stabilization. If the misfire has resulted in active hemorrhage or tissue disruption, direct pressure, suction, and topical hemostatic agents should be promptly employed.<sup>25</sup> It is critical not to forcibly disengage a jammed stapler, which may exacerbate tissue injury. Instead, device-specific troubleshooting steps must be followed—often involving mechanical reversal of the firing sequence or guided disassembly.<sup>26</sup>

Visual inspection of the staple line is indispensable. In cases of incomplete or irregular staple rows, surgeons must carefully assess tissue integrity, vascularity, and approximation. Misfired staples, free or embedded, should be extracted using fine forceps or staple removers to prevent local ischemia or foreign body reactions.<sup>27</sup>

#### Repair options

Management strategy depends on the extent of the misfire and the tissue involved.

Suture reinforcement is often the first step for small staple line defects or bleeding points. Absorbable monofilament sutures in an interrupted fashion can restore apposition and hemostasis.<sup>28</sup>

Re-stapling with a new cartridge may be considered if the tissue is viable and safely accessible. However, staple line overlap must be avoided to prevent ischemia or overcompression, particularly in vascular-rich areas.<sup>29</sup>

Conversion to hand-sewn anastomosis is indicated when misfire results in extensive tissue trauma, ischemia, or device irretrievability. Hand-sewn techniques remain the gold standard in such salvage scenarios, especially in hostile abdomens or when the stapler fails in anatomically constrained locations.<sup>30</sup>

#### Adjunctive measures

Once repair is completed, intraoperative leak testing using air insufflation or dye studies should be performed to confirm anastomotic integrity. This step is particularly vital in low anterior resections and bariatric procedures. Repeat endoscopy may be warranted in high-risk or redo surgeries to assess for submucosal disruption or bleeding points.

Documentation of the misfire event—including device serial number, cartridge type, intraoperative findings, and corrective actions—is essential. This not only fulfills medicolegal obligations but also contributes to institutional quality improvement.

# PREVENTION - DEVICE SELECTION, SURGICAL TECHNIQUE, AND TEAM TRAINING

The most effective way to manage a stapler misfire is to prevent it. Prevention hinges on three pillars: selecting the right device for the tissue, executing meticulous surgical technique, and ensuring the entire surgical team is adequately trained in device handling and troubleshooting. While modern staplers continue to evolve with built-in safety features, the surgeon's vigilance remains irreplaceable.

### Device selection and compatibility

Selecting the correct stapler and cartridge based on tissue thickness and vascularity is paramount. Devices are engineered for specific applications—vascular loads for thin tissue and thick reloads for fibrotic or edematous segments. Misjudgment in cartridge selection is a leading cause of incomplete staple formation or tissue crushing.<sup>31</sup>

Manufacturers have introduced smart staplers with tissuesensing technology that modulate firing based on resistance feedback. While promising, these systems still depend on appropriate placement, full closure, and understanding of device mechanics. Mismatch between reload and application remains a critical failure point even in powered systems.<sup>32</sup>

Surgeons must also be familiar with the technical specifications of various staplers—jaw length, articulation angle, precompression duration, and reload compatibility.

Cross-brand substitutions during surgery without prior orientation may lead to device dysfunction.

#### Surgical technique and best practices

Even with the best equipment, improper use can lead to catastrophic misfires. Surgeons must adhere to core principles.

Precompression for at least 10–15 seconds before firing allows tissue to thin uniformly and reduces staple line bleeding.

Avoid angulated or twisted tissue placement that impairs even staple formation.

Do not force closure or firing if resistance is felt—stop, reassess, and reposition.

Minimize overstacking of staple lines, especially during sleeve gastrectomy or colorectal double-stapling, to avoid ischemia and leak.<sup>33</sup>

Routine inspection of each staple line and conducting air leak tests or dye insufflation prior to desufflation are low-cost, high-yield practices that can identify errors before they become disasters.

### Team training and readiness

Device failure is often not the surgeon's fault alone. Studies suggest that team training significantly reduces operative delays, improves troubleshooting efficiency, and enhances overall patient safety.<sup>34</sup>

Regular simulation-based training—focused on recognizing misfires, safely disengaging devices, and repairing staple line defects—is critical, especially for surgical residents and OR technicians.

Manufacturers, in collaboration with surgical societies, are now developing standardized curriculum modules for stapler training. Such efforts must be expanded and integrated into residency programs and hospital credentialing processes.<sup>35</sup>

Finally, preoperative briefings and team checklists must include device specifications, backup strategies, and agreed-upon salvage plans. Proactive communication and clarity of roles during a misfire can prevent chaos and reduce intraoperative time loss.<sup>36</sup>

# INSIGHTS FROM RANDOMIZED TRIALS AND META-ANALYSES

Randomized controlled trials (RCTs) and systematic reviews have been instrumental in identifying best practices and device performance benchmarks in gastrointestinal stapling. These evidence-based insights help bridge the gap between device innovation and real-world outcomes, especially in the context of misfire prevention, safety, and procedural standardization.

A landmark multicentre RCT compared powered staplers to manual staplers in laparoscopic colorectal surgery, demonstrating that powered systems reduced device misfires and resulted in more consistent staple formation. The study highlighted the benefits of lower actuation force and better ergonomics, particularly in deep pelvic cases.<sup>37</sup> A similar prospective RCT in bariatric surgery reinforced these findings, reporting fewer staple line revisions and reduced intraoperative bleeding in patients operated with powered devices.<sup>38</sup>

Meta-analyses evaluating staple line reinforcement techniques, such as bioabsorbable buttressing and oversewing, revealed a consistent reduction in bleeding and leak-related complications across bariatric and colorectal surgeries. However, these techniques did not completely eliminate failure events, especially in cases involving improper cartridge selection or tissue mismatch.<sup>39</sup>

Another important finding from pooled analyses is that device malfunctions rarely occur in isolation—they are often associated with additional risk factors, including difficult anatomy, poor visibility, and surgeon inexperience. A 2021 meta-analysis suggested that surgical outcomes were most favourable when stapler use was embedded in a structured training and credentialing framework.<sup>40</sup>

Studies evaluating the economic impact of stapler misfires have found that these events are associated with increased operative times, higher conversion rates, prolonged hospital stays, and greater need for ICU-level care—all of which translate into increased healthcare costs.<sup>41</sup>

Finally, recent literature emphasizes the urgent need for uniform adverse event reporting systems to accurately track and quantify stapler misfires. This would not only facilitate cross-comparison of devices but also enhance post-market surveillance and regulatory oversight.<sup>42</sup>

# MEDICOLEGAL IMPLICATIONS AND REPORTING MANDATES

Surgical stapler misfires are not only technical failures they are increasingly viewed through the lens of medical accountability. The medicolegal implications of such events have grown in complexity as device use becomes ubiquitous and patients demand transparency. Failure to document or disclose stapler-related complications may constitute negligence in many legal jurisdictions. 43

Numerous legal cases have highlighted that inadequate documentation of misfires, delayed recognition, and lack of informed consent regarding device use have contributed to unfavourable litigation outcomes.<sup>44</sup> Surgeons must ensure that operative notes clearly state the type of device used, any intraoperative troubleshooting, and corrective steps taken during a misfire.

In 2019, the US FDA reclassified surgical staplers as class II medical devices, citing a substantial number of unreported adverse events and concerns about underreporting by manufacturers and surgeons alike.<sup>45</sup> The move mandated more stringent post-market surveillance, standardized adverse event reporting, and labelling reforms, thus placing greater onus on surgical teams and institutions to report misfires.

Globally, bodies such as the Institute for Healthcare Improvement (IHI) and the World Health Organization (WHO) advocate for transparent reporting frameworks, including the use of surgical safety checklists, device registries, and root cause analysis of intraoperative failures. 46

Hospitals are now encouraged to develop institutional tracking systems that capture device-specific complications and usage patterns, enabling both quality improvement and legal protection in the event of litigation. Failure to report a known misfire may violate hospital policy, ethical norms, and medico-legal standards.<sup>47</sup>

Lastly, informed consent processes should be updated to include discussion of the possibility of device malfunction, especially in high-stakes or high-risk procedures. Documentation of this conversation in the preoperative chart can be a critical legal safeguard.<sup>48</sup>

#### Future directions

The future of stapling safety lies in technology, training, and transparency. Emerging innovations such as tissue-sensing staplers, AI-integrated feedback systems, and smart reloads promise to improve intraoperative decision-making. However, even the most advanced tools cannot substitute for surgeon vigilance, appropriate device selection, and team preparedness.

In parallel, healthcare systems must invest in simulationbased training modules, enforce standardized misfire documentation, and mandate device-specific credentialing. Transparent reporting to regulatory bodies, ongoing surveillance, and feedback-driven innovation from manufacturers will be key to reducing misfire events and optimizing outcomes.

Ultimately, the surgeon remains the last line of defence where judgment, anticipation, and execution converge to protect the patient. A systems-based, humanized, and datadriven approach to stapler use is not just desirable—it is essential.

#### **CONCLUSION**

Surgical staplers have transformed gastrointestinal surgery by enabling precise, rapid, and minimally invasive tissue approximation. Yet, stapler misfires remain a critical threat to patient safety, particularly when they go unrecognized or are poorly managed. This review consolidates current knowledge across device mechanics, intraoperative recognition, management strategies, and prevention—serving as a practical guide for GI surgeons across settings.

#### **ACKNOWLEDGEMENTS**

The authors would like to thank the Department of Surgical Gastroenterology, Indraprastha Apollo Hospitals, New Delhi, for providing access to institutional records and administrative support during manuscript preparation.

Funding: No funding sources Conflict of interest: None declared Ethical approval: Not required

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**Cite this article as:** Kumar S, Bhalerao AS, Gupta S, Tandon V, Govil D. Intraoperative stapler misfire in gastrointestinal surgery: recognition, management, and prevention. Int Surg J 2025;12:1595-601.