



## *Anastomotic Leaks Through Surgeons' Eyes: A Survey-Based Analysis of Attitudes and Perspectives Towards the Stream™ Platform*

*A review of current practices, concerns, and needs among surgeons, and initial impressions of FluidAI's technology for early detection of anastomotic leaks.*

Imagine you are performing a surgical procedure that involves an anastomosis of the gastrointestinal tract. You do your due diligence before, during, and after the surgery to ensure the best outcome for your patient. Everything appears to go as planned, with the procedure successfully completed. During the postoperative period, however, things start to go wrong. Very wrong. Your patient begins to deteriorate rapidly. Further investigations confirm your worst fear: an anastomotic leak (AL).

Despite emergency surgery to try and save your patient, it is too late. They perish. In the wake of this loss, you continue to question: was there anything that could have been done differently to save them? Recognizing that every possible precaution was taken, and anastomotic leaks are an inevitable reality of this type of surgery, you come to a different conclusion:

***If only their leak had been detected earlier, a life might have been saved.***



# INTRODUCTION

Surgeons are no stranger to high-stakes, life-or-death situations, where losing a patient to postoperative complications is a possibility. For those performing surgeries involving anastomoses, the potential for a leak always exists, making complete elimination of this complication an unrealistic approach to improving patient care. Of all postoperative complications, leaks are one of the most serious, carrying high rates of morbidity and mortality, as well as significant economic costs to healthcare systems (1, 2, 3).

Despite the seriousness of AL, little has changed in recent years to improve patient outcomes. While surgical techniques continue to advance, creating an anastomosis still carries the risk of leakage. In order to optimize patient outcomes and minimize the impact of AL, it is imperative that new technologies are developed – but that the voices of surgeons are taken into account during the research and development process. Given the complexity of surgical procedures (not only within the operating room, but also during pre- and post-operative care), taking surgeons' voices into consideration will provide insight into the needs of the medical community, as well as the considerations and evidence new technologies must present before being implemented in clinical settings (4).

To address this need, FluidAI Medical conducted a qualitative assessment of target surgical specialties, aimed at understanding their current views and approaches to AL, as well as initial perceptions of the product concept



for FluidAI's Stream™ Platform. Using pH and conductivity as biomarkers of AL, Stream™ Platform is a simple, effective, and non-invasive means for early detection of AL. This device - which is connected completely external to the patient - monitors drainage fluid continuously, with results easily available for clinicians on a corresponding application.

The findings of this interview-based study are intended to meet several objectives:

- First, to hear first-hand from surgeons about the needs of their field, as well as the challenges currently faced.
- Moreover, these results will help to identify gaps in current clinical practices, research, and technology for detection and/or management of AL.
- This study also provides insight into the ways evidence from new technology such as Stream™ Platform are communicated to potential users, such as the specificity/sensitivity of the device, range of uses, and scope.

While anastomotic leaks are a surgical reality, the morbidity and mortality currently associated with them does not have to be. As the proceeding evidence shows, surgeons are excited about the prospect of a simple, non-invasive tool that holds the power for earlier leak detection.



# METHODS

## Participant recruitment & Survey Process

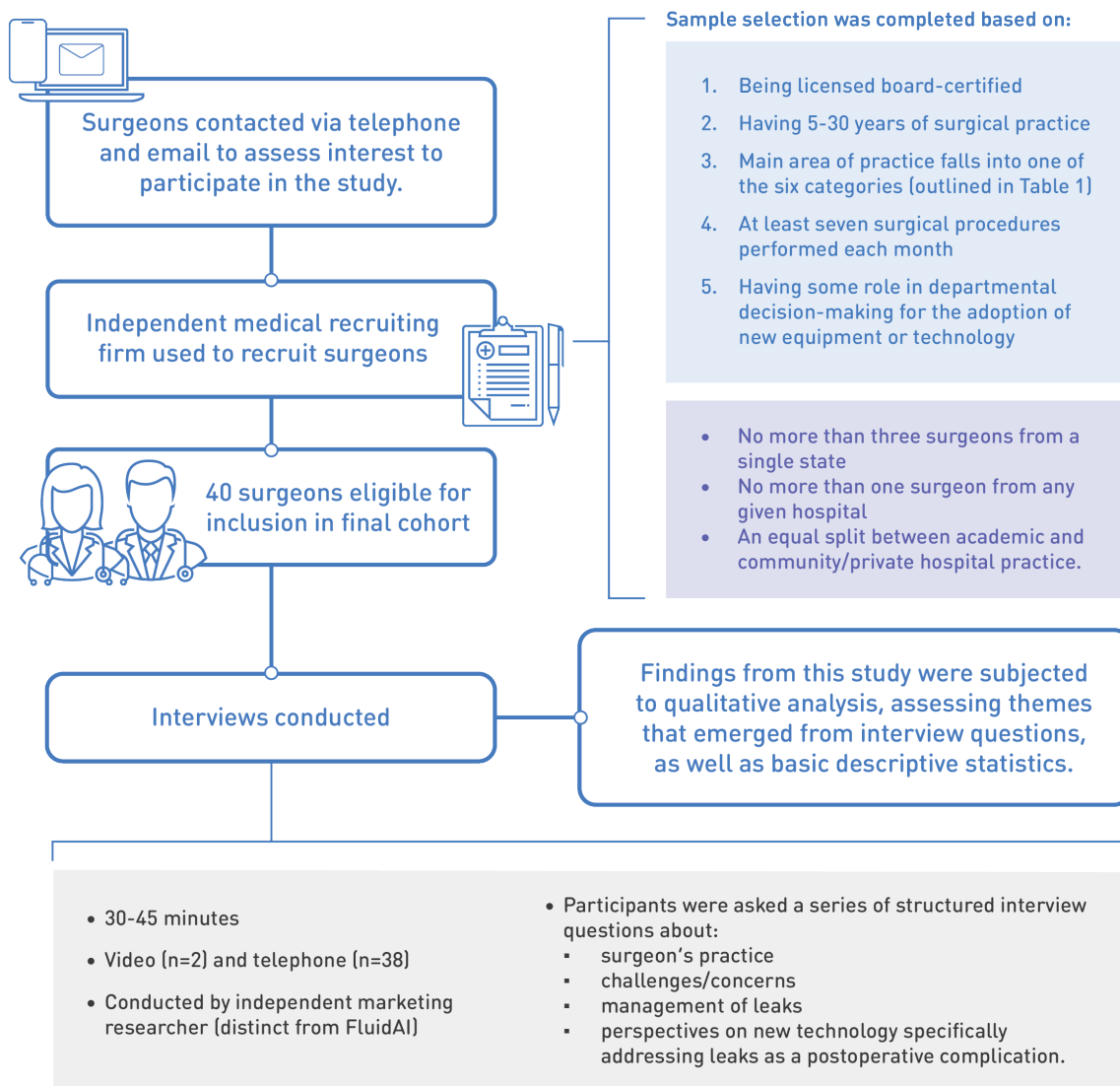


Fig 1. Summary of study methods



Surgeons were contacted via telephone and email to assess interest to participate in the study. An independent medical recruiting firm was used to recruit surgeons. Sample selection was completed based on: (1) Surgeons being licensed board-certified; (2) having 5-30 years of surgical practice; (3) main area of practice fell into one of the six categories outlined in Table 1; (4) at least seven surgical procedures performed each month; and (5) having some role in departmental decision-making for the adoption of new equipment or technology.

Study recruitment guidelines also included no more than three surgeons from a single state, no more than one surgeon from any given hospital, and an equal split between academic and community/private hospital practice. The final cohort consisted of 40 surgeons in total, spread across states and specialties as outlined in Figure 2 and Table 1 below. Average years in practice, as well as average surgeries per month, were also calculated for each surgical cohort.

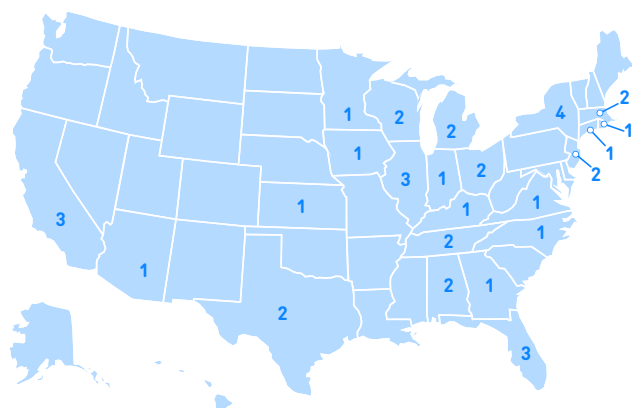


Fig 2 . Geographical distribution of participants

Specialty	Avg Years in Practice	Avg Surgeries per Month
General Surgery (n=7)	23	39
Bariatric Surgery (n=7)	17	41
Colorectal Surgery (n=7)	23	43
Trauma Surgery (n=7)	25	29
Hepato-Biliary / Pancreatic Surgery (n=7)	18	33
Thoracic Surgery (n=5)	11	28

Table 1. Breakdown of specialties, years in practice, and surgeries per month of final participant cohort



Interviews were conducted over video (n=2) or telephone (n=38), and lasted between 30-45 minutes in duration. Honoraria were provided for participation in the study. All interviews were conducted by an independent marketing researcher, distinct from FluidAI. Participants were asked a series of structured interview questions, developed to probe demographic information about a surgeon's practice, challenges/concerns, management of leaks, and perspectives on new technology specifically addressing leaks as a postoperative complication. Participant information was de-identified prior to data analysis.

The findings from this study were subjected to qualitative analysis, assessing themes that emerged from interview questions, as well as basic descriptive statistics.

## FINDINGS & DISCUSSION

Across surgical specialties, the majority of procedures performed by participants were reported to be scheduled, with a smaller proportion made up of emergency or urgent surgeries. Unsurprisingly, the highest proportion of emergent/urgent procedures were performed by trauma surgeons (42%), and fewest in hepatobiliary/pancreatic surgeries (4%). A relatively even split existed between payment for treatment by Medicare/Medicaid and private insurance, with few patients (2-13%, depending on specialty) paying out-of-pocket. A list of the most commonly performed surgeries, as reported by surgeons within each specialty, is provided in [Table 2](#).

Specialty	Procedures
General Surgery	Gall bladder, hernia, bowel, colon, breast, appendix
Bariatric Surgery	Weight loss (sleeve, bypass, revision), hernia, gall bladder
Colorectal Surgery	Anal/rectal, gall bladder, small bowel, colon
Trauma Surgery	Gall bladder, small bowel, hernia, appendix, colon
Hepato-Biliary/ Pancreatic Surgery	Pancreas, liver, bowel, biliary, stomach, colon
Thoracic Surgery	Lung, Esophagus

**Table 2.** Most commonly performed procedures, by specialty



# CONCERNS THAT KEEP SURGEONS AWAKE AT NIGHT

## anastomotic leaks

wound infection  
arrhythmias/myocardial infarction sepsis  
deep vein thrombosis/pulmonary embolism  
bleeding pneumonia

Surgeons reported a variety of significant postoperative concerns, including sepsis (n=7), arrhythmias/myocardial infarction (n=8), pneumonia (n=12), bleeding (n=14), wound infection (n=15), and deep vein thrombosis/pulmonary embolism (n=19). By far, the most significant (and unprompted) concern brought up by surgeons were anastomotic leaks (n=32). In fact, this complication was reported to be so significant that surgeons were 'kept awake at night,' with comments such as the following:

Anastomotic leaks	Bleeding	Sepsis / Infection
"You can do everything perfectly and still get a leak."	"Bleeding patients can deteriorate very quickly."	"These patients become really sick."
"A leaking anastomosis can be catastrophic. The hospital stay can go from days to weeks or even months."		"This can lead to so many other problems. In a patient that's already sick we are potentially looking at organ failure or other complications."
"Patients can die."		
"It often means taking the patient back to the OR and redoing the anastomosis."		

**Table 3.** Direct quotations from participants regarding complications that are significant enough to 'keep them awake at night.'





## HOW IMPORTANT IS EARLY DETECTION OF LEAKS?



In exploring concerns surrounding anastomotic leaks further, the idea of earlier detection was considered to be of great importance across nearly all participants. With earlier detection comes earlier intervention, and the potential to improve patient outcomes significantly. As shown in Figure 3, 95% of surgeons reported early detection of AL to be extremely important or critical, feeling that early detection leads to improved outcomes. Only 5% felt little difference was made in the timing of leak detection.

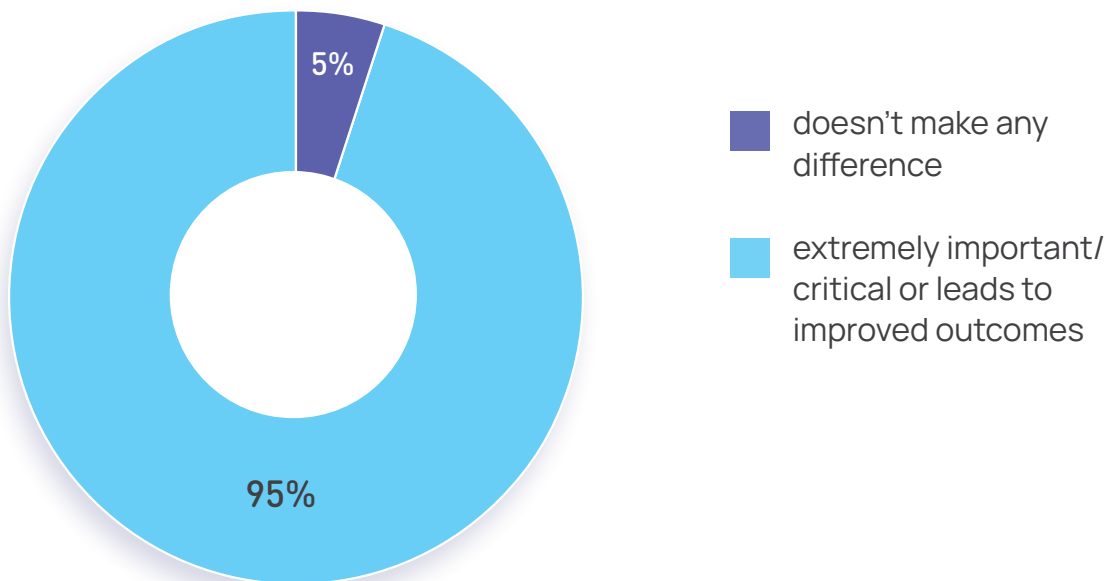


Fig 3. Importance of early detection of anastomotic leaks



Additionally, surgeons acknowledged differences in the management of anastomotic leaks, which often correlates to the time a complication is identified. Less severe leaks may require interventions such as antibiotics, NPO (nothing passing orally by patients), or simply time to recover. The continuum of severity, as demonstrated in Fig. 4, progresses, with interventional radiology sometimes required to drain fluid, stents inserted, and in the worst cases, repeating surgery to repair the anastomosis or temporary stoma. Across the board, sentiments from surgeons were nearly unanimous: “the earlier we can detect the leak, the greater the chance that we can get ahead of it and avoid complications.”

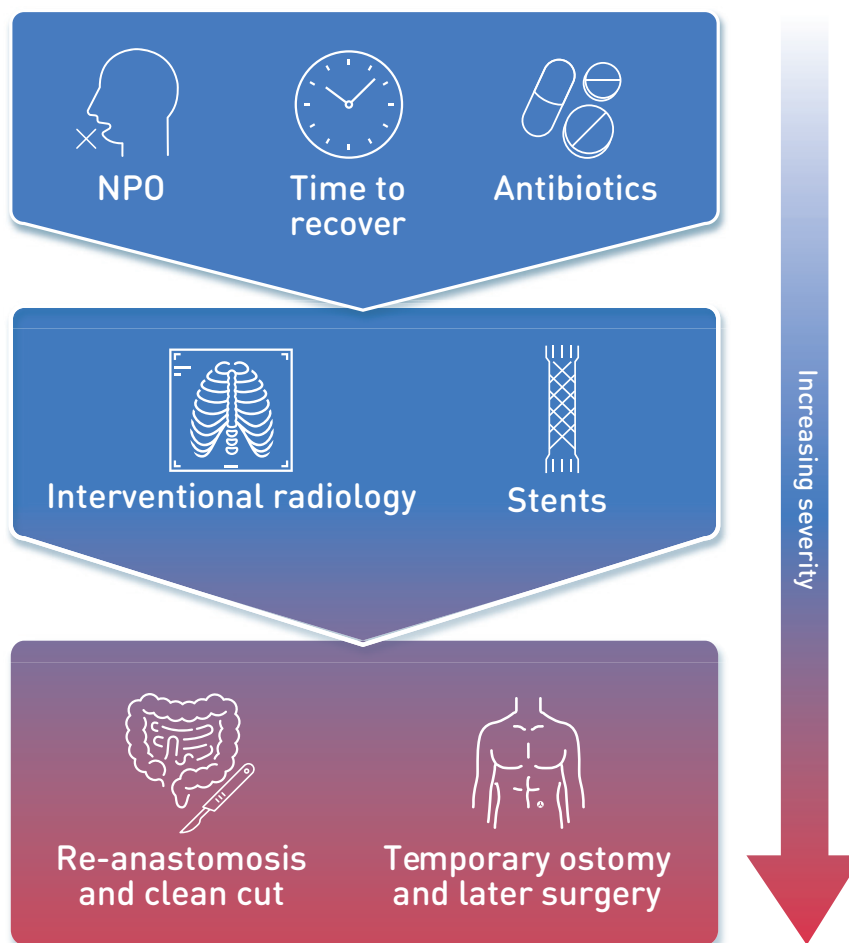


Fig 4. Management of anastomotic leaks, by increasing severity

**“The earlier we can detect the leak, the greater the chance that we can get ahead of it and avoid complications.”**



## WITH AGREEMENT THAT ANASTOMOTIC LEAKS ARE A SIGNIFICANT COMPLICATION, WHAT ARE SURGEONS SAYING ABOUT HOW TO ADDRESS THEM?

Several different unmet needs came up in discussions with surgeons. Some comments suggested that interventional radiologists and gastroenterologists with improved training specifically in detection of AL would be of benefit (n=3). Better imaging technology for evaluating anastomoses was also brought up as a currently unmet need (n=5). However, most enthusiasm surrounded prediction, early detection, and prevention (n=8, 16, and 19, respectively). Knowing which anastomoses have the highest likelihood of leak, at or before the time of surgery, and identifying a leak before patients demonstrate clinical signs of deterioration, were high priorities. Unsurprisingly, prevention techniques, such as better stapling systems, improved surgical techniques, and better sealants, were also popular.

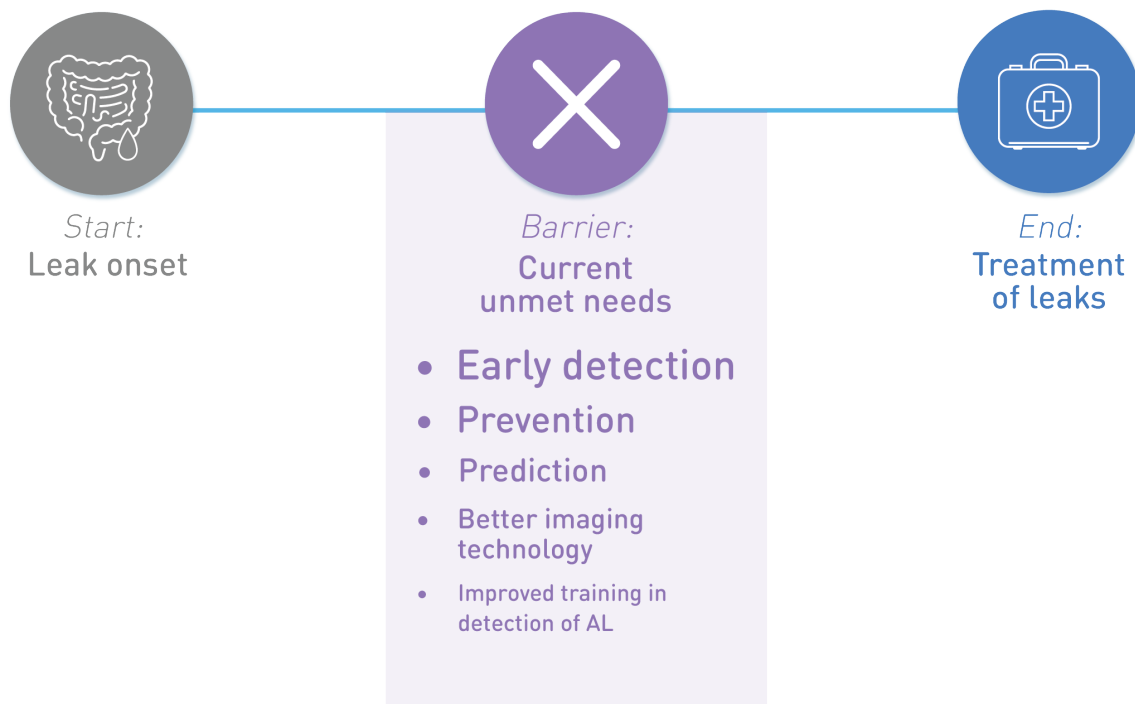
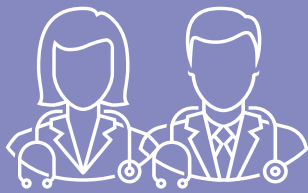


Fig 5. Addressing unmet needs regarding AL



While preventing leaks altogether is clearly ideal, reaching this point has, and continues to be, unsuccessful. Despite other advances in surgery, where there is an anastomosis, the potential exists for an anastomotic leak. Surgeons were asked about recent technologies they were aware of to maximise leak prevention. While some options such as sealants/glues, stents, staplers, and fluorescent imaging were mentioned, a striking 42.5% of participants could not think of any technologies they had acquired in the past three or four years.

As one surgeon described, "I don't think anything has changed in the last six years." The most commonly cited technology was fluorescent imaging (n=14), used to evaluate and monitor vascular perfusion of the anastomosis. Importantly, satisfaction with this technology was moderate, given what is seen as a minimal impact on the course of treatment and/or clinical outcomes. New staples and staplers, expandable stents, and sealants were all met with mediocre success and satisfaction.



**42.5%** of participants could not think of any technologies for leak prevention acquired in the past three or four years.

As one surgeon described, ***"I don't think anything has changed in the last six years."***

Given the less-than-ideal current landscape of technologies to address AL, surgeons were probed for awareness about technologies that may be on the horizon, to advance the management of leaks. Most respondents (70%) had not heard of any new developments to address AL.

Of the 30% who did report they had heard of new technologies, any specifics on these advancements were lacking, but cited possibilities such as improved staples/staple line reinforcement, new coating materials/haemostatic glue, endoluminal vacuums, new stents, antibiotics targeting gut flora, coating gel that changes colour in the presence of a leak, monitoring amylase levels in drains, and monitoring the pH in tissue around the anastomosis.



# A NOVEL SOLUTION ON THE HORIZON: FLUIDAI'S STREAM™ PLATFORM

With this gap in clinical solutions in mind, FluidAI's product concept (non-invasive, real-time monitoring of post-operative drainage fluid as an early predictor of anastomotic leaks) was presented to surgeons. An overall 82% were positive or curious about the technology, with excitement about a non-invasive approach for earlier detection of anastomotic leaks. As one surgeon described, "this is great. People don't die because of leaks, they die because of failure to recognize leaks." Some questions or concerns brought up by participants included financial cost, need for patients to have a drain, and rarity of AL as a postoperative complication. In many cases, simply wanting more information, such as the predictive value of the device, was requested. A summary of perceived benefits and drawbacks reported by surgeons is captured in [Table 4](#).

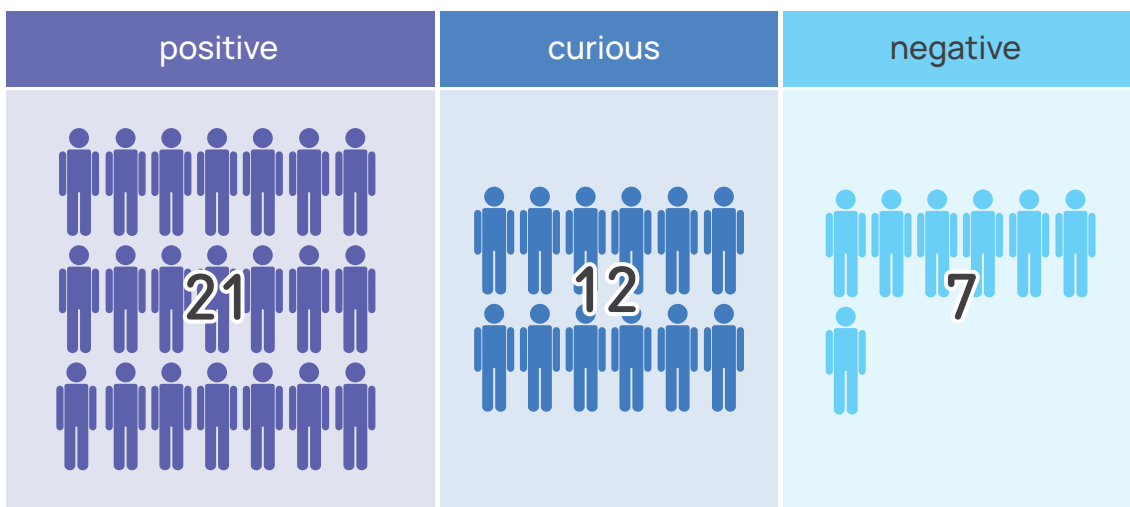


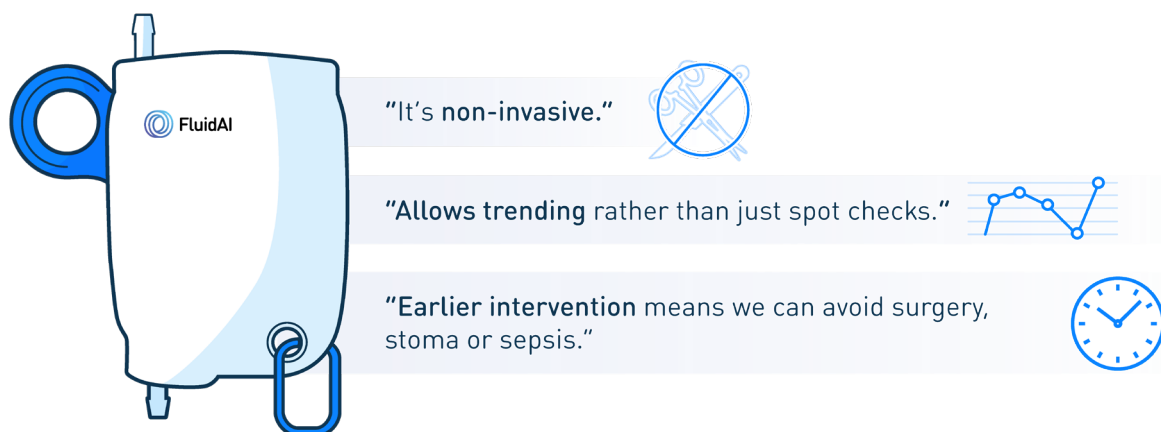
Fig 6. First reaction to FluidAI product concept



**“This is great. People don’t die because of leaks, they die because of failure to recognize leaks.”**

Advantages/Benefits	
“It gives me another data point.”	“It’s non-invasive. It doesn’t add steps.”
“This is good for patients where you don’t want to go back in.”	“We can intervene before there is inflammation.”
“This fills a gap if we can diagnose leaks before they become clinically evident.”	“This will be great for higher risk procedures or patients.”
“This is better than waiting to see if effluent is cloudy.”	“This will help younger, less experienced surgeons.”
“Allows trending rather than just spot checks.”	“We can be more proactive. We don’t have to wait for the patient to get sick.”
	“Earlier intervention means we can avoid surgery, stoma or sepsis.”
Disadvantages/Drawbacks	
“We don’t always use drains.”	“Concerns about false positives, and unnecessary treatment or worry.”
“It’s probably expensive. Leaks are so rare, I’m not sure this would justify any added cost.”	“A false negative could give me a false sense of security.”

**Table 4.** Perceived benefits and drawbacks reported by surgeons



# WHAT DO SURGEONS WANT TO KNOW BEFORE USING A PRODUCT LIKE STREAM™ PLATFORM?

With interest in knowing more about Stream™ Platform, surgeons brought up a number of different questions that would influence their decision to use the device. Of greatest significance was the cost of employing a new technology (62.5%), followed by wanting to review clinical trial data to understand the supporting evidence (40%). False positive and negative rates, sensitivity, and specificity were also brought up by a number of participants (30%, 15%, 22.5%, and 17.5%, respectively). Additional questions surrounded how findings from the device would be interpreted by clinicians, how easy the device was to use and training required, and the overall impact on patient care.



Fig 8. Different aspects that would influence surgeon's decision to use the device



Not all leaks are equal - some are clinical, some are sub-clinical, and feelings about detection varied depending on leak type. Approximately one-third of participants (34%) were interested in knowing about all leaks (clinical and sub-clinical). Reasons for this included the fact that sometimes, sub-clinical leaks can deteriorate, and knowledge about a sub-clinical leak could allow for more conservative care to be provided to patients (e.g. NPO). Other surgeons (24%) only wanted to know about clinical leaks, feeling “[t]here’s such a thing as too much information,” and that awareness of a sub-clinical leak may compel them to run unnecessary tests. Overall, 40% were simply unsure, not having had the possibility for early leak detection in the past, thus requiring more time to reflect on what type of information would be most valuable and optimal for patient outcomes.

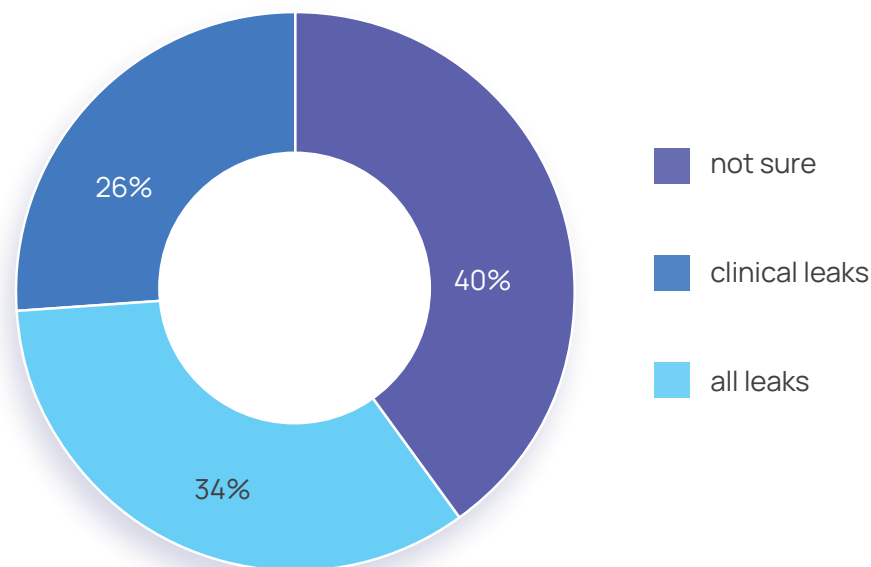


Fig 9. Leaks surgeons want to know about





## WHAT'S THE VERDICT?

Positive outlooks on implementing technology for early detection of anastomotic leaks.

Anastomotic leaks are a worrisome complication, here found to be the most significant postoperative concern reported by surgeons, across specialties. As described, few advancements have been made to manage leaks, and most surgeons have little knowledge about options on the horizon to mitigate the impact of this complication. Given the two greatest unmet needs from surgeons - prevention and early detection - there was excitement and curiosity about the potential of FluidAI's Stream™ Platform as a game-changing technology. Advantages of the device include its ability to be used at the bedside in a non-invasive manner, and that it allows for continuous monitoring rather than measures at single, restricted timepoints.

**The verdict is clear: surgeons have unmet needs, and are calling for creative, effective solutions to improve patient care and provide peace of mind. FluidAI fills a critical gap in post-operative monitoring, providing the potential for these needs to change from hopes to reality.**



# Real-Time Monitoring for Anastomotic Leaks **Stream™ Platform**

by FluidAI



**Interested in  
the technology?**

For more information,  
please contact  
[info@fluidai.md](mailto:info@fluidai.md)



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