# Functional Biosensing for Early Detection of Anastomotic Complications Following Colorectal Resection

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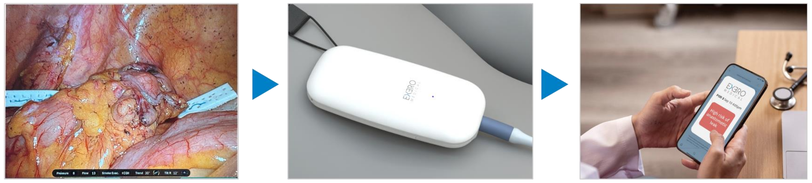
## Objective of the Technology or Device

Anastomotic leak (AL) following colorectal surgery remains a leading cause of morbidity and mortality, yet current detection methods identify leaks only after clinical deterioration has occurred. The goal of this technology is to provide continuous monitoring of tissue recovery parameters at the anastomotic site for early detection of leaks, enabling improved patient outcomes and reduced healthcare costs.

## Device Components



**Sensor placed at anastomosis site**

Embedded in standard surgical drain, no change in procedure

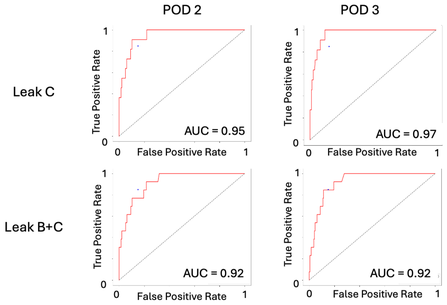
**Small wearable device collects data**

AI algorithm processes data to assess tissue healing status

**Clinician app – decision support**

Data available to support clinician's decisions around patient care

## ROC Curves for Leak Detection by POD and Grade




## Description of the Technology

The xBar System is an implantable, drain-based sensor array designed to monitor local electrophysiological signals from the bowel wall. Integrated microelectrodes within a standard drain are placed adjacent to the anastomosis at the end of surgery. The sensor connects to an electronic device that wirelessly transmits data to a cloud platform for automated analysis. Leak detection algorithms based on electrophysiology identify physiologic patterns indicative of normal healing or impending leak. The device does not require any modification of surgical technique.

## Results

In a prospective multicenter trial, 222 patients undergoing left-sided colorectal anastomosis without diversion were enrolled (47.5% male, mean age 63.2 years). xBar was placed like a surgical drain and recorded data during the first 3 postoperative days with 93.7% technical success (95% CI 89.6–96.5). Severe anastomotic leak occurred in 5.4% (n=12). **On POD3, xBar detected severe leaks with 100% sensitivity** (95% CI 71.5–100) **and 88.3% specificity** (95% CI 83.0–92.5). Mean detection time was 2.4±0.5 days with xBar vs. 6.0±3.5 days clinically, suggesting **>3-day earlier detection with xBar**. No serious device-related adverse events occurred.

## Conclusions and Future Directions

Continuous, local electrophysiological monitoring introduces a new paradigm in postoperative surveillance for colorectal surgery. The xBar System demonstrated safety, technical feasibility, and the potential to detect anastomotic leaks earlier than standard methods. Routine use of xBar is expected to improve outcomes and reduce healthcare cost burden for payers and providers. The rich, unique data the xBar system records may enable rapid development of additional monitoring indications, supporting enhanced recovery and hospital at home paradigms.