

Monitoring of Peritoneal Cavity using Electrode Sensors

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Clinical Context

- Anastomotic leaks are one of the most serious complications after colorectal surgery.
- Leaks lead to significant morbidity and may require re-interventions. The later a leak is detected, the greater the impact to the patient.
- Current postoperative monitoring is indirect and often detects leaks only after clinical deterioration is apparent and the leak has progressed with potentially significant sequelae.
- A technology enabling early identification of patients at risk of leak may reduce complications and hospital length of stay.

Technology Overview

- Electrode array embedded in a standard surgical drain or catheter to collect electrophysiological data directly from the surgical site.
- External cable connects to a small electronic recording device.
- Device transmits data wirelessly to a secure cloud.
- Backend analytics generate a patient-specific anastomotic leak risk score.
- Web application displays risk scores and alerts to clinical teams.
- Pivotal study: Sensitivity 100% and specificity 88% for POD-3 leak detection, >3 days ahead of routine clinical care.

Key Procedural Steps

- Drain/Catheter with embedded electrodes is placed using standard surgical drain insertion techniques.
- Electrodes placed adjacent to the colorectal anastomosis.
- External end consists of a tube which can be connected to a standard drain bulb, and a cable which is connected to a monitoring device.
- Monitoring device collects electrode signals and transmits them wirelessly.
- Clinical team views postoperative data and risk alerts via web application.

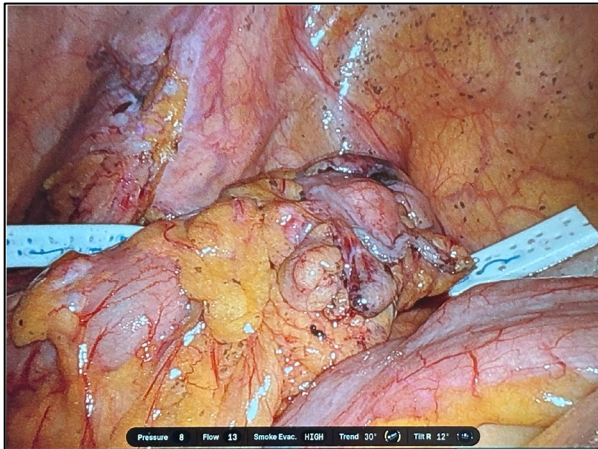


Fig (left): Placement of electrodes adjacent to colorectal anastomosis

Fig (right): Draining tube connected to a drain bulb, cable connected to a monitoring device



Nature of the Device

- Temporary surgical drain or catheter with embedded electrode sensors.
 - Must be used with electronic data transmission device
- Always removed before or at discharge according to standard drain removal procedures.

Anatomic Site Considerations

- Used during colorectal resections involving colon and/or rectum.
- Placement occurs in the abdominal/peritoneal cavity adjacent to the anastomotic site.
- Technology is used in conjunction with colorectal surgery, not standalone.

Distinction From Existing Technologies

- Standard surgical drains do not include sensing capability.
- Monitoring catheters do not integrate with drains or measure anastomotic tissue status.
- No PCS code describes a device serving biosensing functions, including or not including drainage.
- xBar represents a new type of device combining a drain or catheter-like device with active postoperative monitoring.

Impact of Accurate Coding

- Enables precise tracking of use of biosensor-embedded drains.
- Improves postoperative outcomes research in colorectal surgery.
- Supports hospital reporting for NTAP; a New Technology Add-on Payment (NTAP) application will be submitted for future consideration
- Reduces misclassification by providing a dedicated code for this new class of technology.

Summary and Request

- xBar is distinct from existing technologies and not captured by current PCS codes.
- A unique PCS code is needed for insertion of a drain or catheter-like device with embedded electrode sensors.