

Inspection of Upper GI Tract using Ingestible Wireless Capsule

ICD-10 Coordination and
Maintenance Committee Update
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Background

- ▶ Acute Gastrointestinal (GI) Bleeding
 - Potentially life-threatening abdominal emergency
 - Common cause of emergency department visits and hospital admissions
 - Over half a million admissions annually¹
- ▶ Signs and Symptoms²
 - Hematemesis (73%)
 - Melena (21%)
 - Coffee-ground emesis (6%)
 - Vague symptoms: epigastric pain, abdominal tenderness, dizziness

1. Peery AF, Crockett SD, Murphy CC, et al. Burden and cost of gastrointestinal, liver, and pancreatic diseases in the United States: Update 2018. *Gastroenterology* 2019;156:254–72.e11.

2. Owensby, S., Taylor, K., & Wilkins, T. (2015). Diagnosis and Management of Upper Gastrointestinal Bleeding in Children. *The Journal of the American Board of Family Medicine*, 28, 134 LP – 145. 3

PillSense™ GI Bleed Detection System

- ▶ New Procedure for Detecting Upper GI Bleeds
 - Uses an optical sensor in an ingestible wireless capsule
- ▶ System Components
 - Ingestible capsule
 - External real-time receiver



PillSense™ GI Bleed Detection System

- ▶ Functionality of the Capsule
 - Detects blood by analyzing light absorption
 - Displays binary result in real-time as “Blood detected” or “No blood detected”
- ▶ Clinical Benefits
 - Accurate detection within 10 minutes
 - Detects blood as low as 5% in gastric contents
 - Rapid and accurate detection of active upper GI bleeds by the sensor capsule provides important additional clinical data to the physicians for a more effective and efficient triage of patients, use of hospital resources, and decreased hospital stay.



Procedure Description

▶ Initiation

- Turn on the receiver.
- Remove the wireless optical sensor capsule from packaging.

▶ Pairing and Ingestion

- Pair the capsule with the receiver
- Provide the capsule to the patient to swallow with a full glass of water
- Observation by a clinician

▶ Data Acquisition

- Keep receiver near patient until data acquisition completes (typically 10 minutes).
- Wait for "Blood Detected" or "No Blood Detected" message.

Device Utilization

- ▶ Only one device is routinely used
- ▶ Performed as a standalone procedure
- ▶ The capsule passes naturally through the GI tract.

Clinical Trial

- ▶ Prospective open-label, single-arm comparative clinical trial of a novel bleeding sensor for patients with suspected UGIB performed at a tertiary care center¹
- ▶ 126 patients were accrued to the study (59.5% males, mean age 62.4 ± 14.3 years). Sensitivity and specificity for detecting the presence of blood were 92.9% ($p = 0.02$) and 90.6% ($p < 0.001$), respectively.
- ▶ The capsule's positive and negative predictive values were 74.3% and 97.8%, respectively, and positive and negative likelihood ratios were 9.9 and 0.08, respectively. This study indicated the novel bleeding sensor is safe and effective for detecting the presence of blood in patients evaluated for UGIB prior to upper GI endoscopy.

1. Akiki, K., Mahmoud, T., Alqaisieh, M. H., Sayegh, L. N., Lescalleet, K. E., Abu Dayyeh, B. K., Wong Kee Song, L. M., Larson, M. V., Bruining, D. H., Coelho-Prabhu, N., Buttar, N. S., Sedlack, R. E., Chandrasekhara, V., Leggett, C. L., Law, R. J., Rajan, E., Gleeson, F. C., Alexander, J. A., & Storm, A. C. (2023). A Novel Blood-Sensing Capsule for Rapid Detection of Upper Gastrointestinal Bleeding: A Prospective Clinical Trial. *Gastrointestinal Endoscopy*, 1–9. <https://doi.org/10.1016/j.gie.2023.11.051>

Documentation

- ▶ Adverse Events
 - No adverse events reported
- ▶ Medical Record Documentation
 - Documentation would be found in the physician's notes as well as the procedure note
- ▶ Naming conventions to identify use within the patient's chart
 - PillSense
 - GI Bleed detection system or capsule
 - Blood detection capsule