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Tissue Oxygen Saturation Imaging of GI Tract

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Ischemic Tissue

- The potential for tissue ischemia is of high concern in bowel surgery/resection and anastomosis.
  - Insufficient blood perfusion to the tissue can lead to tissue ischemia
    - Partial de-vascularization of the mesentery during bowel resections
    - Torsion and occlusion of the mesenteric vasculature caused by bowel volvulus and intussusception
- Tissue ischemia can lead to tissue necrosis if undetected or untreated.
- Necrotized tissue will allow breakdown of the anastomosis or weakened bowel wall and lead to perforation. This loss of containment of the contents in the GI tract can cause systemic sepsis and multi-organ failure, and may lead to death in serious cases.

1: *Matthias Pross et al, Gastrointestinal Endoscopy, Vol 51, Issue 1, Jan 2000, Pages 73-76*
2: *E. Rullier et al, Br J Surg, 85(1998), pp. 355 - 358*
3: *Roggo A, Ottinger LW. Ann Surg 1992;216(2):135-41*
4: *Iwuagwu O, Deans GT. Small bowel volvulus: a review. J R Coll Surg Edinb 1999;44(3):150-5*

Tissue Oxygen Saturation Imaging

- Minimally invasive surgeries are typically performed through one or more small incisions, using a small video camera and surgical instruments.
- Physicians perform these surgical procedures using the instruments inserted in the body cavity while observing endoscopic images of the surgical site provided by the camera.
- Existing endoscopic imaging systems provide physicians with full-color video images on a monitor as they would see with their naked eyes during open surgery
- Fluorescence imaging with indocyanine green (ICG) dye has been used to help visualize blood flow. However, there are limitations to this technique:
  - Requires intravenous injection of ICG dye prior to the imaging
  - Duration of fluorescent observation of the GI tract is limited due to filtration of ICG dye in the liver
  - Not currently available for endoscopy
- Current technology for endoscopic imaging *does not* allow physicians to visualize oxygen saturation of the tissue.

Visualization of Tissue Oxygen Saturation Levels With the EP-7000X System

- The EP-7000X System - Oxygen Saturation Endoscopic Imaging (OXEI) is a new technology that allows for the visualization of tissue oxygen saturation (StO_2) levels of the gastrointestinal tract using a 2D endoscopic image (laparoscopic and endoscopic) during surgery. This allows physicians to identify tissue which is not appropriately oxygenated and thus potentially ischemic.
- The technology can be used in many different applications where ischemic tissue in the gastrointestinal tract may be observed:
  - Gastrointestinal resection and anastomosis (e.g. esophagectomy, gastrectomy, small bowel resection, colectomy)
  - Hernia and abdominal wall reconstructive procedures
  - Treatment of bowel volvulus and intussusception
  - Endoscopic examination following the above surgical procedures
- Anticipated use in both inpatient and outpatient procedures
- There are no known adverse events associated with use of the EP-7000X System
- Documented in the operative report and OR record; likely identified as tissue oxygen saturation imaging

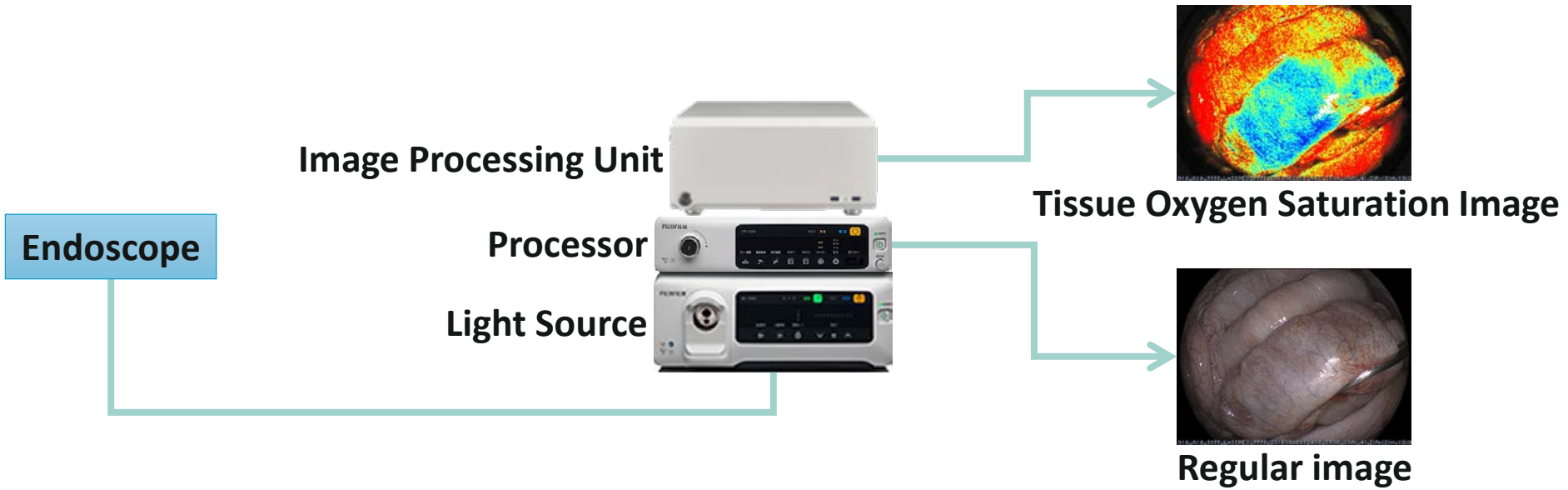
The EP-7000X System

- Received Breakthrough Device designation from the Food and Drug Administration (FDA) on September 17, 2020
- 510(k) application submitted December 18, 2020; clearance anticipated before June 30, 2021
- Expected indications based on 510(k) submission:
  - Intended for use as an adjunctive monitor of the tissue oxygen saturation of gastrointestinal tract of the endoscopic observation image area in patients at risk for ischemic states
  - May be used on all patients requiring endoscopic examination of gastrointestinal tract including stomach, small and large intestines and rectum

Oxygen Saturation Endoscopic Imaging - OXEI

Visualization of tissue oxygen saturation of gastrointestinal tract in endoscopic images

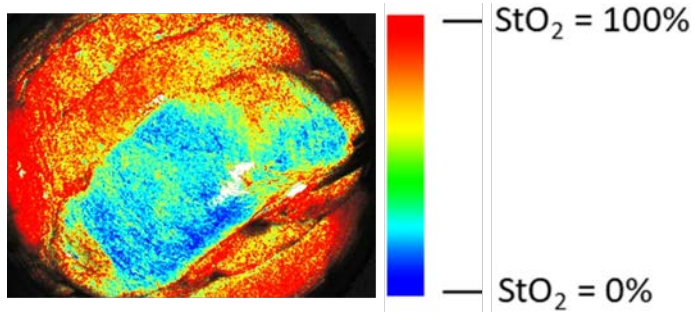
- Measures StO_2 of superficial tissue
- Provides two-dimensional StO_2 map of the tissue under endoscopic image
- Provides StO_2 image and regular endoscopic image simultaneously in real time



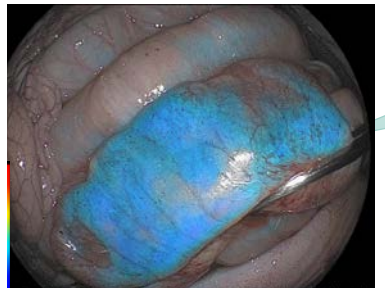
Oxygen Saturation Endoscopic Imaging – OXEI (cont'd)

Provides two types of StO_2 images

- OXEI-P mode provides multi-colored map associated with StO_2



- OXEI-F mode provides overlay image that has StO_2 image over regular image.



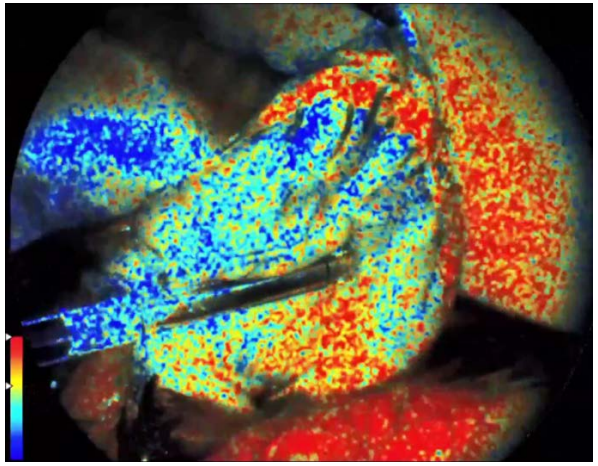
OXEI – Percutaneous Endoscopic Approach

- Procedural steps:
  - Physicians perform minimally invasive surgeries using endoscope and surgical instruments inserted in the body cavity through small incisions while observing endoscopic images
  - The OXEI modes are turned on/off by user pressing a switch on the endoscope handle or on the light source anytime when the user wants to observe tissue oxygen saturation of the surgical site in the endoscopic image

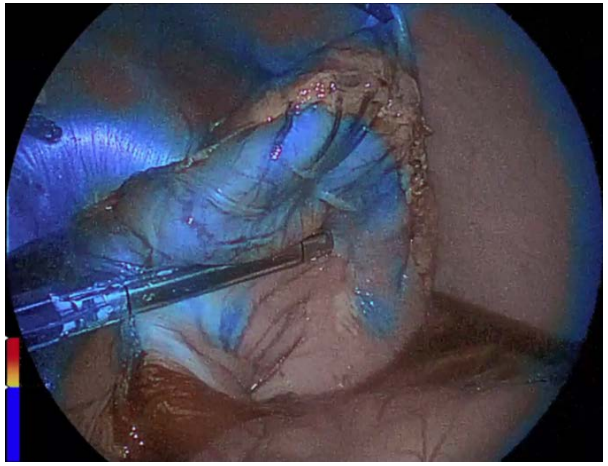
- Image examples of swine stomach:

Regular image

OXEI-P mode



OXEI-F mode

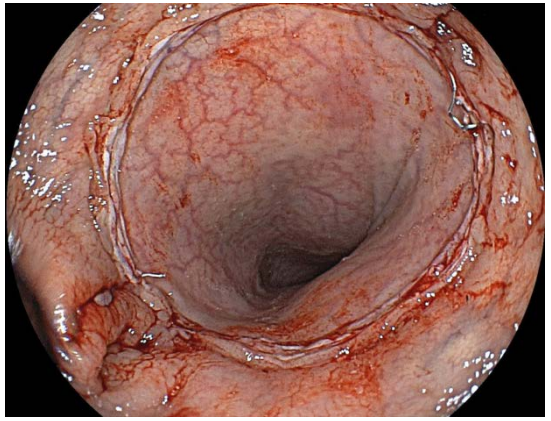


OXEI – Natural Orifice Endoscopic Approach

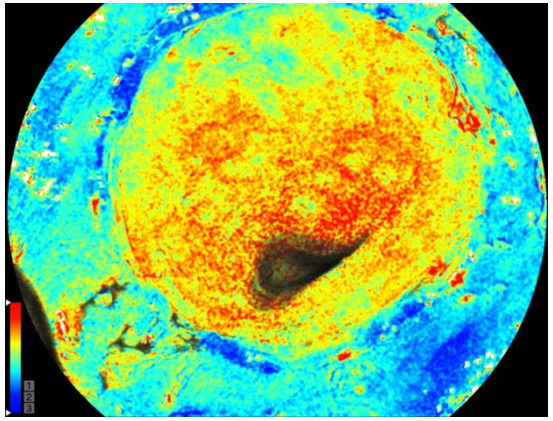
- Procedural steps:
  - Physician inserts a endoscope through the patient's mouth or anus into the GI tract depending on part of the GI tract examined
  - The OXEI feature is turned on/off by user pressing a switch on the endoscope handle or on the light source anytime when the user wants to observe tissue oxygen saturation of the site in the endoscopic image

- Image examples of swine bowel:

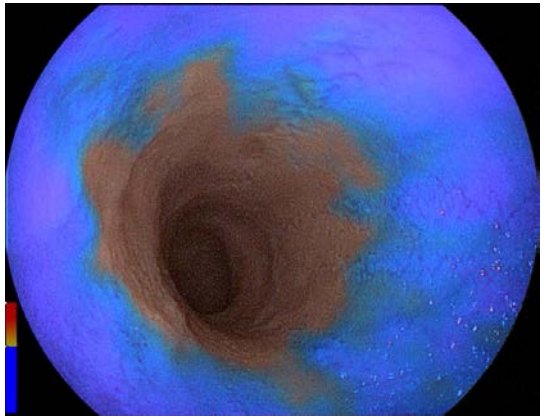
Regular image



OXEI-P mode



OXEI-F mode



Need for a Unique ICD-10-PCS Code

- OXEI provides an adjunctive monitor to measure in real time the tissue oxygen saturation and potentially assist physician to identify ischemic areas that are at risk of tissue necrosis.
- While there are a number of ICD-10-PCS codes to describe the minimally invasive surgeries in abdominal, gynecologic, thoracic, and endoscopic examination in gastrointestinal tract areas in which tissue oxygen saturation imaging would also be performed, none of them signal the performance of tissue oxygen saturation imaging as a separate service during the procedure.
- FUJIFILM requests that unique ICD-10-PCS codes be created to describe tissue oxygen saturation imaging in support of a submitted New Technology Add-on Payment application.

Thank you