

*Converging Robotics & AI...a new vision of GI diagnostic & therapeutic excellence*

# NAVICAM<sup>®</sup> *Stomach System*

**Sedation-Free,  
Robotically-  
Controlled,  
Capsule  
Endoscopy**



## Exclusive Features of the NaviCam® Stomach System

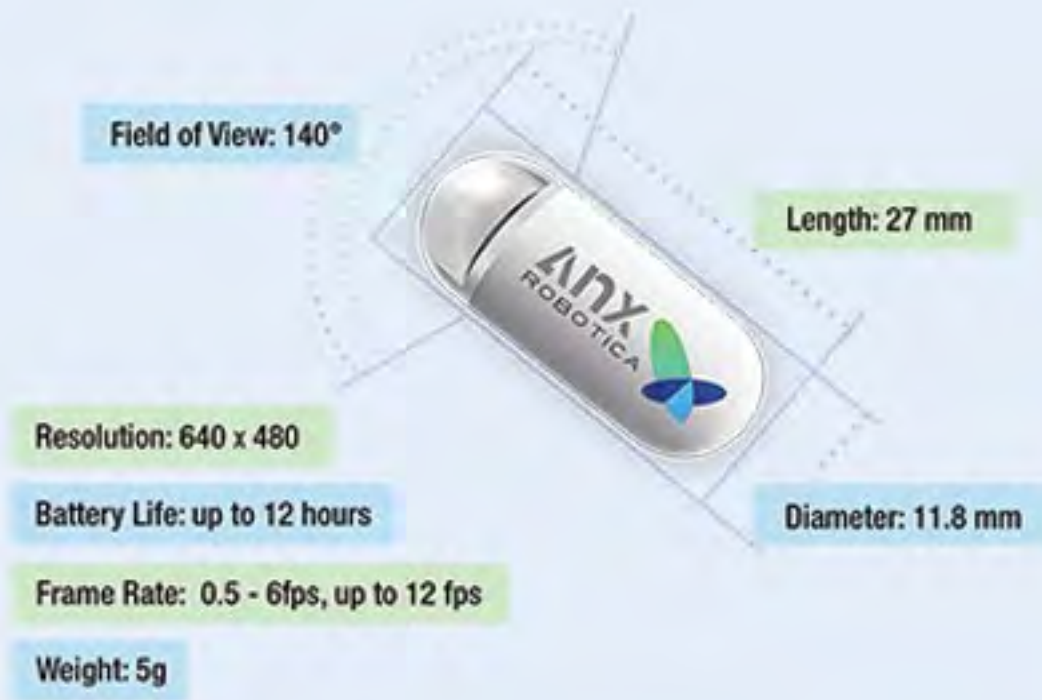
### NAVICAM® CONTROLLER

- **Translational Rotation Platform:** Includes a 5D motion system (3D linear motion and 2D rotation motion, achieving three-axis linear motion and two-axis rotation motion of the magnet during examination).
- **Examination Bed:** Controls for import or export movement, facilitating patient to get on and off the examination bed conveniently.
- **Magnetic Head:** Generates corresponding magnetic field by adjusting motion of the magnet to control the motion of the capsule endoscope inside the human body.

### PATIENT CONSOLE

- **Console:** The NaviCam Stomach console consists of the control panel, computer and ESNavi™ software. The operator is able to control the motion of the platform and capsule as well as related tasks including image processing.
- **Control Panel:** Includes two joysticks, which are used to control the magnetic head.
- **Computer:** Receives signaling from the control panel and ESNavi™ software and transmits to translational rotation platform.
- **ESNavi™ Software:** Displays the interface for controlling, browsing, and video monitoring.

## NaviCam® Stomach Capsule Technical Information



*Conventional gastroscopy allows for the accurate localization of lesions and is the most effective diagnostic modality for gastric diseases.*

*Sedation can improve patient compliance, but its cost has been a major concern, as well as discomfort and anesthesia-related adverse events that are encountered in a few patients after the procedure.<sup>2</sup>*

*Traditional capsule endoscopy is propelled by natural motility and gravity of the digestive tract, including the stomach. These limitations have traditionally prevented complete visualization of the gastric cavity.*

## **NaviCam® Stomach Capsule Endoscopy System**

Introducing the NaviCam® Stomach Capsule System, an advanced technology that combines magnetic control with innovative and intelligent software to give medical practitioners external robotic control of the capsule inside the human body. The minimally invasive procedure with NaviCam® can be guided in real-time in five dimensions (two rotational and three translational planes) by a physician from a control console.

In a large, prospective, multi-center blinded study, the NaviCam® Stomach System was shown to be a safe method of visualizing the gastric mucosa through remote magnetic manipulation without the need for intubation or sedation.<sup>1</sup>

The NaviCam Stomach System can be used in clinics and hospitals, including the ER setting and is intended for adults ( $\geq 22$  years old) with a BMI less than 38.



### **The First 360° Robotic-Controlled Stomach Capsule- Revolutionizing Capsule Endoscopy**

The system incorporates three-dimension translational and two-dimension rotational control to guide precise movement of the capsule inside the stomach.

## NaviCam® Benefits



- The risk of perforation and cross-contamination is minimized with MCCE.
- NaviCam® can navigate a 180 degree turn in order to view the esophageal sphincter.
- MCCE can view the stomach in its natural state rather than the sedated invasive state, which is important for the diagnosis of motility conditions such as gastroparesis.

### The Sedation-Free Alternative<sup>3</sup>

Because NaviCam® Stomach Procedures do not require sedation, patients can resume normal activities following the procedure. NaviCam® also provides an alternative to those patients in which sedation is contraindicated due to co-morbidities, or health risk.

### Hospital or Clinic-Based

The physician can perform stomach capsule endoscopies at either the hospital or the clinic. If procedures are performed in the hospital, the staff does not have to set up an Endoscopy Room (as with an EGD), or in the Endoscopy Suite of the Endo Center and ASC. This potentially saves costs, time and resources associated with the facility, anesthesia and personnel, just to name a few.

Placement of NaviCam® in the clinic may offer an economically favorable option which may reduce facility costs.

## NaviCam® Components

### Capsule

The ingestible capsule is a pill-sized video camera that the patient swallows with water before starting the examination. Inside the capsule is a tiny camera that has its own light source; it takes pictures of the patient's stomach while its movement is controlled by the physician.

### Data Recorder

The Data Recorder is worn over clothes for the examination. It is used to receive the picture images within the stomach that are captured by the capsule during the examination.

### Capsule Locator

The locator is used by the physician or nurse to activate the capsule before it is ingested by the patient. The locator is also used when the patient, post procedure, is concerned that the capsule that they ingested may not have been excreted. The locator can determine if the capsule is indeed still within the digestive tract.

### ESNavi™ Software

In a Real-Time View Panel, or Screen, on the left of the Physician Console, the software displays the actual anatomical view, a recently captured image(s), and a toolbar with various functional icons for working with the NaviCam® Stomach System. In addition, on this same screen, images and videos taken during the procedure can be studied and exported while viewing the image displayed, or captured, along with "schematic" views.

1. Clinical Gastroenterology and Hepatology 2016;14:1266–1273

2. Ibid

3. Adverse events reported by the patients were reported in approximately 1% of patients, and mild in nature including abdominal distension, nausea, vomiting and headache. These adverse events were attributed to the preparation. In all patients this was resolved within 24 hours.

## NaviCam® Clinical Evidence

In a landmark clinical study, MCCE (the NaviCam® Stomach System) was compared to conventional gastroscopy. The results were published in *Clinical Gastroenterology and Hepatology* 2016;14:1266–1273. The following are excerpts from that paper:

### Accuracy of Magnetically Controlled Capsule Endoscopy, Compared With Conventional Gastroscopy, in Detection of Gastric Diseases. Zhuan Liao,\*et. al.

**Background & Aims:** ... It is impossible to visualize the entire stomach with the passive capsule currently used in practice because of the large size of the gastric cavity. A magnetically controlled capsule endoscopy system (MCCE) has been designed to explore the stomach...

**Results:** ... focal lesions in the whole stomach with 90.4% sensitivity (95% confidence interval [CI], 84.7%–96.1%)... detected focal lesions in the upper stomach (cardia, fundus, and body) with 90.2% sensitivity (95% CI, 82.0%–98.4%) and 96.7% specificity (95% CI, 94.4%–98.9%)... focal lesions in the lower stomach (angulus, antrum, and pylorus) with 90.6% sensitivity (95% CI, 82.7%–98.4%) and 97.9% specificity (95% CI, 96.1%–99.7%)... (NaviCam®) did not miss any lesions of significance (including tumors or large ulcers).

**Discussions:** MCCE could be a reliable filter test to stratify patients into those without relevant lesions not requiring further invasive methods, such as gastroscopy.

In this study, there were 110 patients (31.4%) who required biopsy by gastroscopy. Nearly 70% of patients did not need an invasive gastroscopy after MCCE examination. Second, MCCE would be a promising alternative for high-risk patients with peptic ulcers or gastric cancer, ensuring that early lesions would be detected.

**Conclusions:** ... NaviCam® detects focal lesions in the upper and lower stomach with comparable accuracy with conventional gastroscopy... is preferred by almost all patients, compared with gastroscopy, and can be used to **screen gastric diseases without sedation.**



Figure 1. Representative polyps observed on conventional gastroscopy and MCCE. (A–C) MCCE examination and (D–F) gastroscopy.



Figure 2. Representative ulcers observed on conventional gastroscopy and MCCE. (A and B) Benign ulcers observed by MCCE, (C) malignant ulcers observed by MCCE, and (D–F) the corresponding ulcer images observed by gastroscopy.

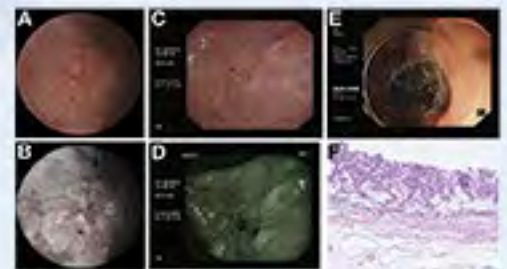


Figure 3. Early gastric cancer was observed on MCCE and conventional gastroscopy. (A) MCCE, (B) narrow-band imaging by MCCE, (C) gastroscopy, (D) narrow-band imaging by gastroscopy, (E) endoscopy submucosal dissection, and (F) pathology.



Figure 4. Representative images illustrating gastric focal lesions missed by MCCE or gastroscopy. Upper panel: lesions missed by MCCE. (A) Polyp, (B) small ulcer, and (C) submucosal tumor. Lower panel: lesions missed by the first gastroscopy. (D and E) Polyps and (F) gastric diverticulum.

## AnX Robotica Corporation

*Founded in 2019 as an advanced technology medical device company integrating innovative research and development with the mission of providing the medical community with patient-friendly devices for diagnostic and therapeutic applications.*

Headquartered in Plano, Texas, AnX Robotica was granted a De Novo classification by the FDA for the NaviCam® Stomach System, the world's first commercialized robotic control platform for gastrointestinal visualization. AnX Robotica is working to expand the NaviCam® platform for various additional diagnostic aids and therapeutic applications.

AnX Robotica's NaviCam® Stomach System has achieved a medical milestone by enabling the ability to perform a stomach examination with a minimally invasive, patient-friendly procedure while giving the physician complete control. By simply swallowing a pill-sized capsule, patients can undergo a thorough stomach examination without the need for sedation. The technology has been utilized in over a half-million patients worldwide, including over 160,000 patients in 2020 alone.

With the innovation of the NaviCam® "Magnetically Controlled Capsule Endoscopy (MCCE) System," AnX Robotica has

developed a new method of minimally invasive thorough visualization of the stomach with comparable performance to gastroscopy for the stomach – *the gold standard*. Our latest software application for small bowel endoscopy, ProScan™, incorporates a deep learning algorithm to identify and differentiate subtypes of abnormal lesions (NaviCam® SB with ProScan™ is not yet cleared for marketing in the U.S.) and was recognized as a "New Era for Diagnosis of Small Bowel Disease." Notably, it was highlighted on the cover page of "Gastroenterology," in October 2019.

The NaviCam® Stomach System utilizes advanced robotic technologies combined with innovative and intelligent software to give physicians external robotic control of capsules inside the human body. In addition to the NaviCam® Stomach System, AnX Robotica also markets IntraMarX and IntraMarX 3D, a radioopaque marker for colonic transit testing, in the US. In current development are other relevant technologies such as NaviCam® SB for Small Bowel, NaviCam® UGI, NaviCam® Colon and Vibrabot™, a capsule for the treatment of constipation.



AnX Robotica  
6010 W. Spring Creek Pkwy  
Plano, TX 75024  
855.777.0020 or 469.606.9495  
info@anxrobotics.com

### NaviCam Disclaimer

AnX Robotica's NaviCam software includes optional functionalities and features designed to assist healthcare providers in operating the NaviCam system.

Providers shall have the sole and exclusive responsibility for operating the NaviCam software and system and for choosing to use NaviCam's optional functionalities and features. Providers shall operate the NaviCam software and system in compliance with all applicable federal and state legal requirements and the requirements of all applicable professional licensing boards relating to providers' professional medical services. Providers using the NaviCam software and system are solely responsible for interpreting data resulting from the use of the NaviCam software and system and for providing medical services and advice to their patients.

AnX Robotica does not provide medical advice or perform medical services. Providers shall operate the NaviCam software and system, including any optional functionalities and features, in their sole discretion, using their professional judgment. The NaviCam software and system is not intended in any way to replace Providers' independent medical review and analysis.