

EvoEndo[®] Single-Use Endoscopy System

Allows patients five and older to undergo a transnasal or transoral EGD exam without anesthesia.



Executive Summary

The narrative surrounding the use of general anesthesia in endoscopic diagnostic exams is evolving and is encouraging pediatric and adult healthcare professionals in the GI community to look for lower-risk, sedation-free alternatives.

The EvoEndo[®] Single-Use Endoscopy System is uniquely positioned to support this evolution in care by enabling sedation-free transnasal (TNE) endoscopic examinations of the upper gastrointestinal tract without the use of general anesthesia.

The EvoEndo[®] Single-Use Endoscopy System is the only product on the market that packs high-definition image quality, the choice of 110 cm or 85 cm scope lengths to cover the esophagus to the duodenum, 4-way steering, air/water/suction functionality, and a 2.0 mm working channel for accessories into an ultra-slim 3.5 mm diameter disposable scope.

Background

The total volume of endoscopic examinations to diagnose, monitor, and treat various conditions of the upper gastrointestinal tract number more than eight million cases annually in the United States across all patient populations. Most of these endoscopic examinations are performed transorally under general anesthesia.

In 2016, the United States Food & Drug Administration (FDA) issued a drug safety communication statement resulting in label changes the following year regarding the use of general anesthetic and sedation medicines in children younger than three years.

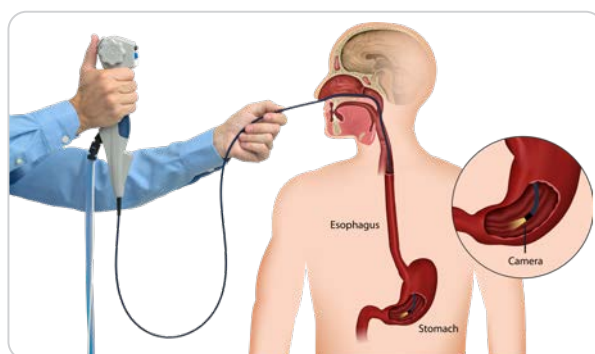
- [FDA Drug Safety Communication: FDA approves label changes for use of general anesthetic and sedation drugs in young children^I](https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-approves-label-changes-use-general-anesthetic-and-sedation-drugs-in-young-children)

The announcement spurred further discussions and clinical studies that seek to clarify the underlying mechanics behind age-dependent effects of anesthetic agents on developing brains.

- [Frontiers Editorial: Anesthetic neurotoxicity in developing brains: mechanisms, biomarkers, and therapeutic targets^{II}](https://www.frontiersin.org/articles/10.3389/fneur.2023.1279529/full)
- [Anesthesia and Developing Brains: Unanswered Questions and Proposed Paths Forward^{III}](https://www.smarttots.org/wp-content/uploads/2022/09/AnesthesiaDevelopingBrains-UnansweredQuestionsPathForward.pdf)

While this topic is still under debate, with more research required to make any definitive statements beyond what the FDA has already published, the pediatric healthcare professional and parent communities have already taken notice.

As a result, within the last few years there has been an increase in pediatric medical centers performing sedation-free transnasal upper tract endoscopy (TNE). Initially, the primary use of TNE at these locations has been limited to the diagnosis and management of Eosinophilic Esophagitis (EoE). However, according to existing published literature, transnasal endoscopy does not need to be limited to the esophagus and stomach but can also be used to safely examine through the gastric body to the proximal portion of the duodenum (EGD). This allows many other conditions (e.g., Celiac disease, carbohydrate malabsorption, ulcers, etc.) to be evaluated. Multiple studies are currently underway that examine the efficacy of diagnostic sedation-free TNE for multiple indications.



^I <https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-approves-label-changes-use-general-anesthetic-and-sedation-drugs>

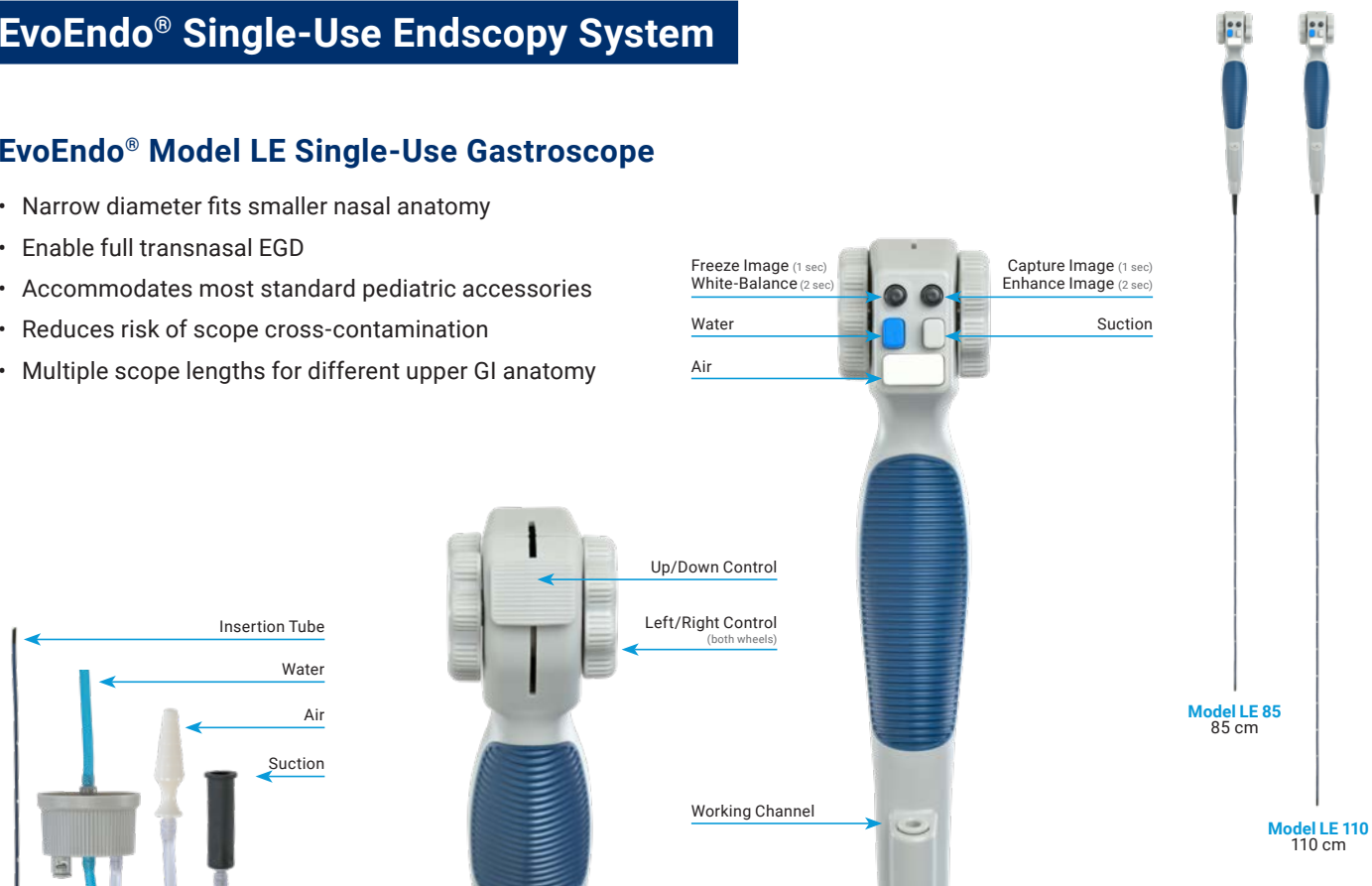
^{II} <https://www.frontiersin.org/articles/10.3389/fneur.2023.1279529/full>

^{III} <https://www.smarttots.org/wp-content/uploads/2022/09/AnesthesiaDevelopingBrains-UnansweredQuestionsPathForward.pdf>

EvoEndo® Single-Use Endoscopy System

EvoEndo® Model LE Single-Use Gastroscope

- Narrow diameter fits smaller nasal anatomy
- Enable full transnasal EGD
- Accommodates most standard pediatric accessories
- Reduces risk of scope cross-contamination
- Multiple scope lengths for different upper GI anatomy



Indications for Use

The EvoEndo® Model LE Gastroscope is intended for the visualization of the upper digestive tract in adults and pediatric patients, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb in patients over the age of five. The gastroscope is a sterile, single-use device and can be inserted orally or transnasally. The EvoEndo® Controller is intended for use with an EvoEndo® Endoscope for endoscopic diagnosis, treatment, and video observation.

EvoEndo® Controller

- Lightweight and portable at 6" x 8.5", 2 lbs
- Easy to set up - plug and play
- Enables scaling to multiple sites
- Allows integration with some third-party endoscopy reporting software (e.g., Provation)



EvoEndo® Patient Experience Kit

- Virtual reality patient distraction via single-use VR goggles
- Stress-relief squeeze ball
- Curated, age-appropriate video library at evoendo.com/youtube



Patient Benefits

Safety

- No needles, no anesthesia.
- No risk of infection from cross-contamination.

Convenience

- Quicker recovery.
- Less fasting time, less time in clinic, less disruption.
- Reduces burden on caregivers.
- Can scope more frequently.

Patient-Centric

- Distraction techniques improve the patient experience.
- Family or caregiver can accompany patient during the procedure.
- Healthcare professional can discuss visual findings immediately.

The safety and convenience benefits of EvoEndo® Sedation-Free TNE lower barriers to care and allow patients and families to spend less time in the procedure room and more time enjoying the activities they love.

Healthcare Professional Benefits

Efficiency

- More procedures in less time.
- No waiting for scope reprocessing and repairs.
- Easy to operate, small footprint, highly portable.

Improved Outcomes

- Faster time to diagnosis.
- Better access and fewer barriers to care for patients.
- Well-tolerated by the majority of patients with a 94% - 98% success rate.^{6,8,10}
- Increases patient compliance.

Risk Mitigation

- Reduces complication potential related to anesthesia.
- Eliminates cross-contamination risk from scope reprocessing.

EvoEndo® Sedation-Free TNE reduces the barriers to care for patients and increases access for a larger proportion of the treatment population, leading to better outcomes while improving clinician efficiency and decreasing risk.

Healthcare System Benefits

Improved Economics

- Adds an additional revenue stream through increased procedural throughput.
- Reduces total cost of ownership.
- Stabilizes operational budget expenditures.

Better Resource Management

- Frees up expensive, OR-based treatment areas for higher-margin procedures.
- Reduces procedural backlogs.
- Improves patient no-show rates by decreasing wait times.
- Eliminates staff downtime for reprocessing or repair of reusable scopes.
- Less staff required to support the same volume of procedures.

Scalability

- Low capital costs and minimal start-up costs enable rapid program expansion.
- System portability can transform underutilized spaces to revenue generating procedure sites.

The addition of EvoEndo® Sedation-Free TNE to existing GI service lines will provide new revenue opportunities and potentially make existing lines more efficient and profitable through improved resource allocation and management. These adjustments reduce patient backlogs and improve access to essential services throughout the division.

Evidence-Based Practice Summary

Sedation-free upper gastrointestinal endoscopy, also known as unsedated endoscopy, has been available and reported in the United States and around the world since 1994.¹ Originally developed by an adult physician, ultra-thin endoscopes were developed to enable transnasal insertion during the sedation-free procedure.¹ Evaluation of the upper GI tract could include the esophagus, stomach, and/or small intestine.^{2,3} The transnasal approach, called TNE, was noted to be more comfortable than transoral insertion without sedation. Compared to the EvoEndo® Model LE Gastroscope, the diameter of most competing endoscopes is usually equal to or greater than 5 mm (about 0.2 in) in diameter and sacrifices various features to accommodate the smaller size. Multiple studies using these devices documenting their safety, reliability, and ease of learning have been published in medical literature. However, even with these reports, adoption has mostly been limited to otolaryngologists in the United States and gastroenterologists internationally for a variety of reasons.³ The manuscripts, with case-series sometimes greater than 1,000 patients, highlighted use of TNE for the evaluation of reflux, Barrett's esophagus, esophageal varices, enteral tube placement, esophageal strictures, GI screening, and first-line diagnosis in elderly or high risk-patients.^{4,5,6} Several pieces of literature about the technique can be found on the EvoEndo website and other educational resources.

Most recently, sedation-free endoscopy in pediatrics has prompted a resurgence of the technology in the United States, primarily around the care of patients with eosinophilic esophagitis (EoE).⁷⁻¹¹ There are now more studies in the pediatric population that have documented reliable biopsies, increased patient safety, improved efficiency, cost/charge savings, high success rate, and high patient satisfaction.⁷⁻¹⁰ Most of the pediatric studies, however, used flexible endoscopic devices not cleared for Upper GI endoscopy and missing features of gastroscopes.^{7, 8, 12, 13, 14} In February 2022, EvoEndo released a full featured gastroscope, cleared for use in patients five years and older to perform transnasal and transoral evaluation of the upper GI tract. Since 2022, more than 900 endoscopies with the EvoEndo® Single-Use Endoscopy System have been performed in the pediatric and adult population with a success rate greater than 98%.⁸ Most physician use has been for EoE monitoring but others have used the device for evaluation of duodenitis, gastritis, H. Pylori Culture, or dysphagia. By fall of 2023, 10 research abstracts have been published at scientific meetings.¹⁵⁻²⁰ These publications highlight developing new sedation-free endoscopy programs with the EvoEndo training system, device use success rates in various populations, use in esophageal varices, and the first multi-center case series. Additionally, two manuscripts about the technology for sedation-free procedures have been submitted. One recently accepted publication is about the device's use for transnasal esophagogastroduodenoscopy (TN-EGD) in the pediatric office-based setting. EvoEndo's device has been transformative for more than 25 medical centers around the United States.

Research Featuring EvoEndo

Papers Published in Peer Reviewed Journals

Proof of Concept Functional Endoscopic Esophageal Evaluation of Swallowing (FEEES) Using Unsedated Transnasal Endoscopy

Friedlander J., Smith C., Nguyen N., Mark J., Prager J., DeBoer E., Deterding R., Belkind-Gerson J.
<https://onlinelibrary.wiley.com/doi/10.1002/jpn3.12154>

A Guide on Transnasal Endoscopy: Setting up a Pediatric Unsedated Endoscopy Program

Friedlander, Joel A., Kristina Leinwand, Vrinda Bhardwaj, and Nathalie Nguyen.
[Front. Pediatr., January 2024; Sec. Pediatric Gastroenterology, Hepatology and Nutrition, Volume 11 - 2023](#)

Safety and Efficacy of a Novel Ultrathin Gastroscope for Unsedated Transnasal Endoscopy in Children and Adults for Evaluation of Upper Gastrointestinal Disorders

Thavamani A, Ryan M, Leinwand K, Ramraj R, Schroeder A, Menard-Katcher P, Bhardwaj V, Franciosi J, Friedlander J, Sabe R
[iGIE, 2024: E-Pub](#)

Office-Based Sedation-Free Transnasal Esophagogastroduodenoscopy (TN-EGD) With Biopsies Using Single-Use Gastroscopes: A Pediatric Single-Center Experience

Smadi Y, Thomas J, Bittar K, Norton H, Friedlander JA, Bornstein J
[JPGN Reports, 2023: 1-6](#)

Scientific Abstracts Published or Presented at Scientific Meetings

[ABSTRACT \(PRESENTED DDW 2024\)](#)

Sedation-Free Transnasal Upper Endoscopy with Biopsies using Virtual Reality Distraction Can Evaluate the Upper Gastrointestinal Tract in Adult Research Subjects

Sarah McGill, Christina Gainey, Scott Commins, Joel Friedlander

[ABSTRACT \(PRESENTED DDW 2024\)](#)

Sedation-Free Transnasal Endoscopy (TNE) Using Single-Use Ultra-Slim Gastroscopes in an Ambulatory Esophageal Clinic

Domenico Farina, Katherine Hanley, Srinadh Komanduri

[ABSTRACT \(PRESENTED DDW 2024\)](#)

Use of a Single-Use Sterile Ultra-Slim Gastroscope for Pediatric Unsedated Transnasal Endoscopy (uTNE)

Patricia Dowds, Molly Phelan, Edisio Semeao, Joel Friedlander, Matthew Ryan

[ABSTRACT \(PRESENTED NASPGHAN 2023\)](#)

Transnasal Endoscopy for Eosinophilic Esophagitis Using the Single-Use EvoEndo Endoscope

Beinvogl B, Taffe M, Pizzi AM, Rubinstein E

[ABSTRACT \(PRESENTED NASPGHAN 2023\)](#)

Use of a Single-Sterile Use Gastroscope for Pediatric Unsedated Transnasal Endoscopy (UTNE)

Dowds P, Phelan M, Semeao E, Friedlander J, Ryan M




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- 3 Tanuma, Tokuma, Yoshinori Morita, and Hisashi Doyama. 2016. "Current Status of Transnasal Endoscopy Worldwide Using Ultrathin Videoscope for Upper Gastrointestinal Tract." *Digestive Endoscopy: Official Journal of the Japan Gastroenterological Endoscopy Society* 28 Suppl 1 (April): 25–31.
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- 9 Scherer, Corey, Peri Sosensky, Dena Schulman-Green, Meredith Levy, Clinton Smith, Joel Friedlander, and Alex Koral. 2021. "Pediatric Patients' and Parents' Perspectives of Unsedated Transnasal Endoscopy in Eosinophilic Esophagitis: A Qualitative Descriptive Study." *Journal of Pediatric Gastroenterology and Nutrition* 72 (4): 558–62.
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We achieve **big things** through **small scopes.**

Our ultra-slim technology unleashes the potential of sedation-free endoscopy to improve the lives of patients, families, and healthcare professionals.

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About EvoEndo

EvoEndo® Inc. was founded by passionate physicians dedicated to developing a safer, sedation-free option for patients requiring frequent endoscopic examinations. The EvoEndo® Single-Use Endoscopy System allows patients five and older to undergo a sedation-free transnasal EGD exam. EvoEndo's sterile, portable, ultra-slim 3.5 mm gastroscope with lengths of either 85 cm or 110 cm and a 2 mm working channel, is specifically designed to enable the endoscopic observation, diagnosis, and treatment of the esophagus, stomach, and duodenal bulb.

This system was cleared for use by the FDA in February of 2022, and has been adopted by over 25 hospitals looking to build sedation-free endoscopy programs for their patients.