evoendo
Evolving Endoscopy

EvoEndo Single-Use Endoscopy System

Value Analysis Presentation

Agenda

- Evolution of Sedation-Free Endoscopy
- Evidence-Based Practice Summary
- The EvoEndo Endoscopy System
- Benefits and Implementation Value
- Reimbursement and Coding Support

Limitations of Traditional Upper Endoscopy

Significant infrastructure and resources required for cleaning and reprocessing scopes

Existing scopes are **expensive** and require **frequent repair**

Too large for sedation-free TNE: Require anesthesia and potential patient risk

Doctors, patients, and families are looking for lower-risk, sedation-free alternatives.

Evidence-Based Practice Summary

- Sedation-free TNE has been available and reported in the United States and around the world since 1994. Multiple studies document its safety, reliability, and ease of learning.
- Studies in the pediatric population have documented reliable biopsies, increased patient safety, improved efficiency, cost/charge savings, high success rate, and high patient satisfaction

300+

Published articles on TNE

NIH National Library of Medicine

Highlighted Publications Featuring EvoEndo

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

Smadi Y, Bittar K, et al. JPGN Reports, 2023: E-Pub

https://onlinelibrary.wiley.com/doi/10.1002/jpr3.12025

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, et al. iGIE, 2024: E-Pub

https://www.researchgate.net/publication/376790857_Safety_and_Efficacy_of_a_Novel_Ultrathin_Gastroscope_for_Unsedated_Transnasal_Endoscopy_in_Children_and_Adults_for_Evaluation_of_Upper_Gastrointestinal_Disorders

Click Here for Additional Literature

The Future of Endoscopy is Here

The EvoEndo Endoscopy System is the only FDA-cleared product designed specifically for pediatric patients of all ages, enabling traditional transoral endoscopy and introducing a sedation-free, lower-risk, and cost-effective alternative.

Safety

- **Sedation-free TNE eliminates the need for general anesthesia**
- **Single-use design decreases the risk of cross-contamination**

Efficiency

- **Reduced NPO time, no pre- or post-procedure recovery time**
- **A functional scope is always available, no reprocessing time required**

Affordability

- **Lower up-front capital expenses**
- **No scope maintenance, repairs, or reprocessing costs**

Productivity

- **Frees up sedated treatment areas for higher-margin procedures**
- **Reduces procedural backlogs**
- **Improved patient no-show rates by decreasing wait times**
- **Relieves staffing/anesthesia shortages**

EvoEndo Single-Use Endoscopy System

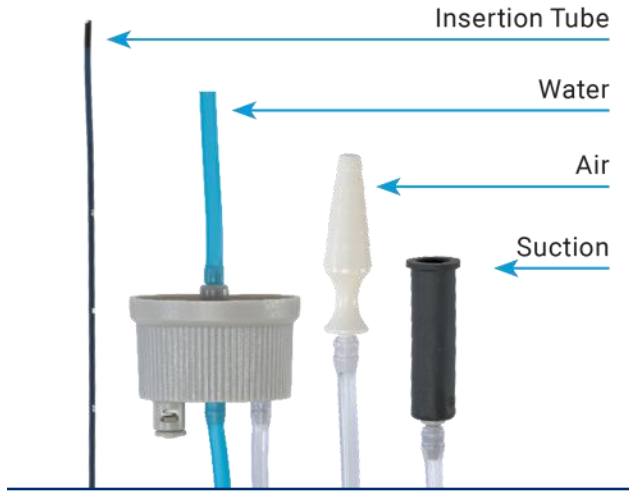
Indications for Use

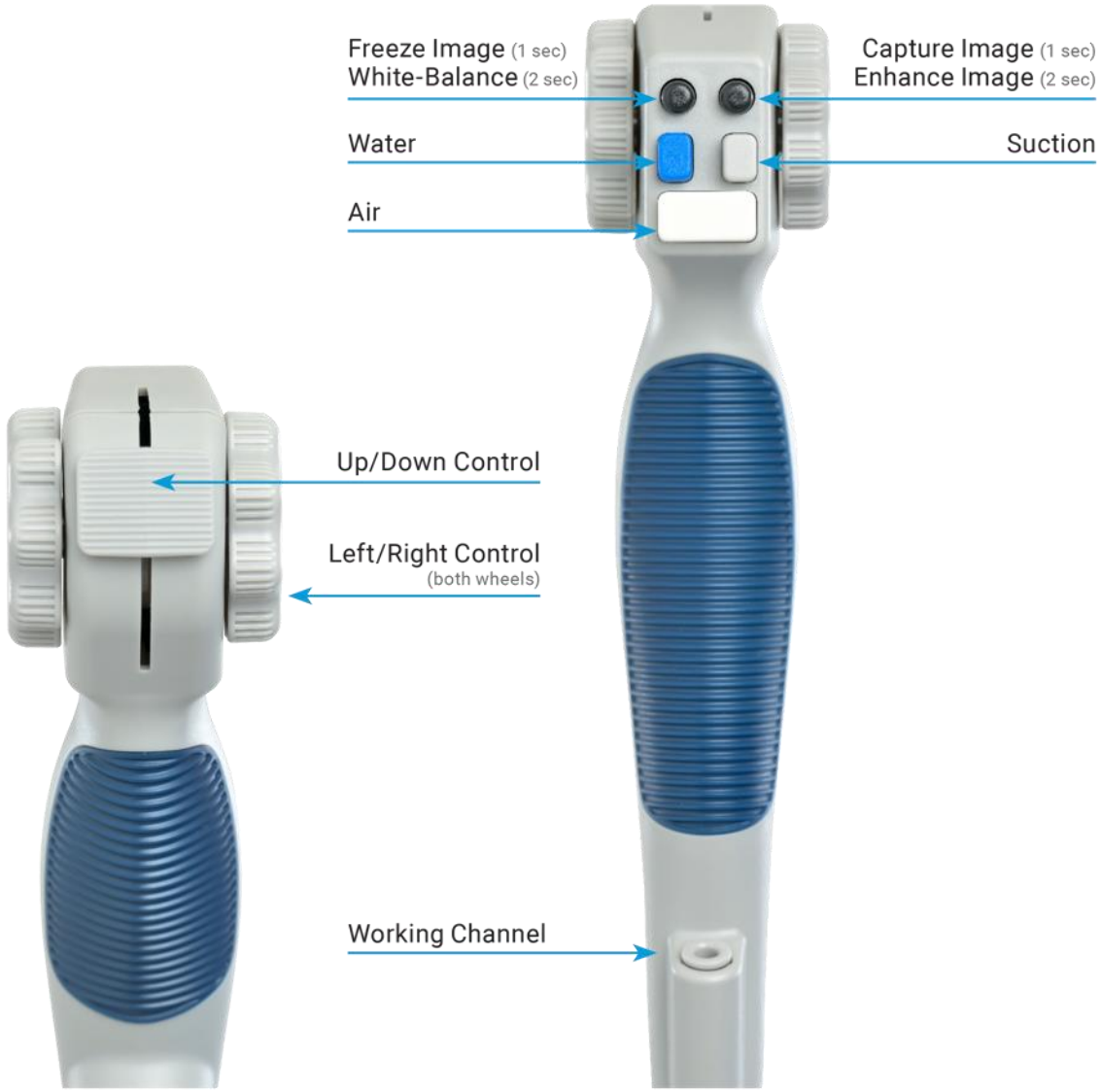
The EvoEndo Model LE Gastroscope is intended for the visualization of the upper digestive tract in adults and pediatric patients, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb. The gastroscope is a sterile, single-use device and can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

EvoEndo Model LE Single-Use Gastroscope

Product Specifications

- Narrow diameter fits smaller nasal anatomy
- Enables full transnasal EGD
- ChannelMax™ technology accommodates most standard pediatric accessories
- Reduces risk of scope cross-contamination





EvoEndo Controller

- Lightweight and portable at 6” x 8.5”, 2 lbs
- Easy to set up – plug and play
- Easy to scale to multiple sites
- Integrates with some third-party endoscopy reporting software (e.g., Provation)

EvoEndo Patient Experience Kit[1]

- Virtual reality patient distraction via single-use VR goggles[2]
- Stress-relief squeeze ball
- Curated, age-appropriate video library at evoendo.com/youtube

1. EvoEndo Patient Experience Kit is not part of the cleared EvoEndo System
2. Phone required, not included

Patient Benefits

Safe

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

Convenient

- Quicker recovery
- Less fasting time, less time in clinic, less disruption
- Reduced burden on caregivers
- More frequent scoping

Patient-Centric

- Distraction techniques improve the patient experience
- Family may accompany patient during the procedure
- Visual findings can be discussed immediately

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

Healthcare System Benefits

Improved Economics

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

Better Resource Management

- Frees up 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
- Reduces 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 into revenue-generating procedure sites

Implementation Value with the EvoEndo System

Clinical Support & Training

- In-service training on TNE and the EvoEndo System
- Head model and demo equipment for practice
- Detailed instructions, workbooks, videos, and checklists
- Guidance on preparing patients and families
- Onsite support for first cases
- TNEase™ Scoring System for measuring success
- Visiting Physician Program for peer training and support
- Network of KOLs and TNE providers
- User group for collaboration and support
- Educational webinars

Implementation Planning

- Materials for preparing your site and equipment
- Best practices for TNE methods and staffing
- Procedure workflow suggestions, tips, and tricks

Program Launch & Expansion

- Patient education website, materials, and videos
- Recruiting tools and templates
- Digital marketing templates and best practices

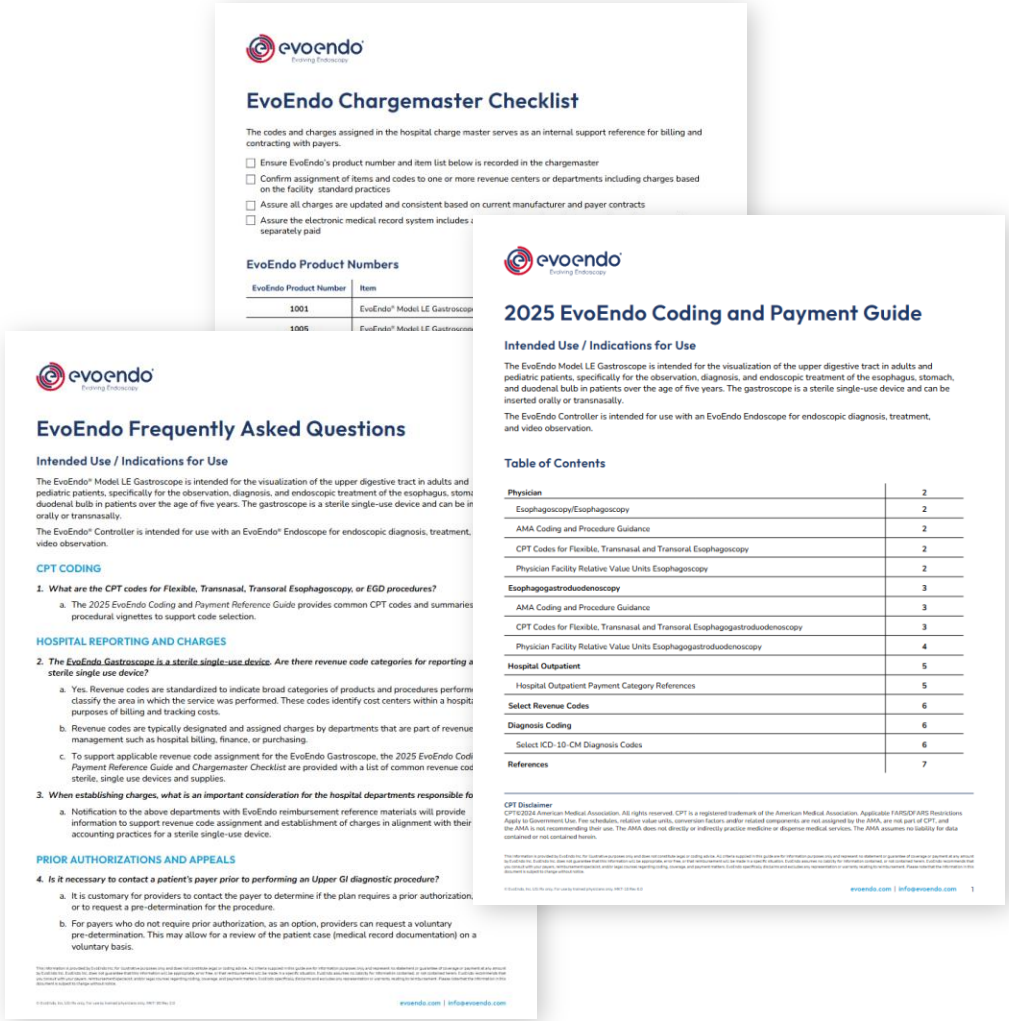
Business Planning

- Reimbursement and chargemaster resources
- Preparation materials for your Value Analysis Committee
- Models for estimating economic value
- Program start-up checklist and templates
- Library of evidence-based literature and scientific abstracts

"The EvoEndo team was incredible in brainstorming ways for our group to provide even more high-value care to our patients. They worked diligently with our administration to implement an accessible cart for mobile use of the EvoEndo System. This has been revolutionary, allowing us to provide care in the emergency department, ICU, and on the inpatient wards more easily."

— PAUL TRAN, MD
Pediatric Gastroenterologist

Coding and Reimbursement Support



EvoEndo Chargemaster Checklist

The codes and charges assigned in the hospital charge master serves as an internal support reference for billing and contracting with payers.

- ☐ Ensure EvoEndo's product number and item list below is recorded in the chargemaster
- ☐ Confirm assignment of items and codes to one or more revenue centers or departments including charges based on the facility standard practices
- ☐ Assure all charges are updated and consistent based on current manufacturer and payer contracts
- ☐ Assure the electronic medical record system includes a separately paid

EvoEndo Product Numbers

EvoEndo Product Number	Item
1001	EvoEndo® Model LE Gastroscop
1005	EvoEndo® Model LE Gastroscop

EvoEndo Frequently Asked Questions

Intended Use / 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, stoma duodenal bulb in patients over the age of five years. The gastroscope is a sterile single-use device and can be in orally or transnasally.

The EvoEndo® Controller is intended for use with an EvoEndo® Endoscope for endoscopic diagnosis, treatment, video observation.

CPT CODING

1. *What are the CPT codes for Flexible, Transnasal, Transoral Esophagoscopy, or EGD procedures?*
   a. The *2025 EvoEndo Coding and Payment Reference Guide* provides common CPT codes and summaries procedural vignettes to support code selection.

HOSPITAL REPORTING AND CHARGES

2. *The EvoEndo Gastroscope is a sterile single-use device. Are there revenue code categories for reporting a sterile single use device?*
   a. Yes. Revenue codes are standardized to indicate broad categories of products and procedures perform classify the area in which the service was performed. These codes identify cost centers within a hospit purposes of billing and tracking costs.
   b. Revenue codes are typically designated and assigned charges by departments that are part of revenue management such as hospital billing, finance, or purchasing.
   c. To support applicable revenue code assignment for the EvoEndo Gastroscope, the *2025 EvoEndo Codi Payment Reference Guide* and *Chargemaster Checklist* are provided with a list of common revenue cod sterile, single use devices and supplies.
3. *When establishing charges, what is an important consideration for the hospital departments responsible fo*
   a. Notification to the above departments with EvoEndo reimbursement reference materials will provide information to support revenue code assignment and establishment of charges in alignment with their accounting practices for a sterile single-use device.

PRIOR AUTHORIZATIONS AND APPEALS

4. *Is it necessary to contact a patient's payer prior to performing an Upper GI diagnostic procedure?*
   a. It is customary for providers to contact the payer to determine if the plan requires a prior authorization, or to request a pre-determination for the procedure.
   b. For payers who do not require prior authorization, as an option, providers can request a voluntary pre-determination. This may allow for a review of the patient case (medical record documentation) on a voluntary basis.

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2025 EvoEndo Coding and Payment Guide

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Table of Contents

CPT Disclaimer

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Supporting Documents

- EvoEndo Coding and Payment Guide
- EvoEndo Chargemaster Fact Sheet
- EvoEndo Chargemaster Checklist
- EvoEndo Frequently Asked Questions
- EvoEndo Reimbursement Glossary and Acronym Reference
- EvoEndo Adult Medicine Coding and Payment Guide
- EvoEndo Adult Medicine Chargemaster Checklist

Contact Us for More Information

303.223.7445

sales@evoendo.com

evoendo® | Expanding Access | Elevating Care

Optional Additional Material

EvoEndo Model LE Single-Use Gastroscope

Product Specifications

Optical System	
Field of View	120° Diagonal, 87.5° Horizontal
Depth of Field	2.5 mm – 25 mm
Illumination method	LED
Insertion Portion	
Bending section	210° Up, 90° Down, 100° Left, 100° Right
Maximum diameter of insertion portion	3.5 mm (0.14”)
Working length	1.1 M or 85 cm
Channel	
Average inner diameter	2.0 mm (0.078”)
Minimum instrument channel width	2.0 mm (0.078”)
Connections	
Air Connector	Connects to 1/4”– 3/8” supply lines
Water Connector	Connects to bottle with 1.25” top
Suction Connector	Connects to standard 6 mm suction device

Featured Literature Highlighting EvoEndo

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, et al.
iGIE, 2024: E-Pub

This study aimed to evaluate the safety and efficacy of a novel ultrathin gastroscope specifically designed for unsedated transnasal endoscopy, with a particular focus on its application in both pediatric and adult populations presenting with various upper GI conditions.

https://www.researchgate.net/publication/376790857_Safety_and_Efficacy_of_a_Novel_Ultrathin_Gastroscope_for_Unsedated_Transnasal_Endoscopy_in_Children_and_Adults_for_Evaluation_of_Upper_Gastrointestinal_Disorders

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

Smadi Y, Bittar K, et al. JPGN Reports, 2023: E-Pub

This study aimed to evaluate the feasibility and efficacy of office-based sedation-free transnasal esophagogastroduodenoscopy (TN-EGD) using single-use gastroscopes in pediatric patients.

https://onlinelibrary.wiley.com/doi/10.1002/jpr3.12025

Featured Literature Highlighting EvoEndo

Left lateral decubitus (LLD) position during sedation-free transnasal endoscopy: A pilot study

Rose Lee, Yonna Oparaugo, Molly Mackensen, Katherine Vaidy

This pilot study explores the feasibility and tolerance of TNE used for TN-Eso and TN-EGD and in pediatric patients using the LLD position.

https://onlinelibrary.wiley.com/doi/full/10.1002/jpr3.70047

A Case Series of Rapid Resolution of Pediatric Eosinophilic Esophagitis with Dupilumab Treatment as Demonstrated by Sedation-Free Transnasal Esophagoscopy (TN-Eso)

Arsal Khan, Isabel N. O'Connell, Wayne G. Shreffler, Joel A. Friedlander, Qian Yuan

This study demonstrates excellent tolerance of TN-Eso done by a newly-trained sedation-free endoscopist. It demonstrated TN-Eso is a useful tool in a research environment which helped find that patients with EoE had an earlier response (3-4 weeks) to dupilumab treatment.

https://www.scientificarchives.com/article/a-case-series-of-rapid-resolution-of-pediatric-eosinophilic-esophagitis-with-dupilumab-treatment-as-demonstrated-by-sedation-free-transnasal-esophagoscopy-tn-eso

Featured Literature Highlighting EvoEndo

The mouth or the nose: the past, present, and future of ultra-slim gastroscopy of the upper gastrointestinal tract in pediatrics

Paul Tran, Rose Lee, Ali Mencin, Matthew Ryan, Joel A. Friedlander, Michael A. Manfredi

This manuscript reviews the techniques and clinical utility of ultra-slim flexible endoscopes. It highlights the value such technology offers to pediatric providers and healthcare systems.

https://www.frontiersin.org/journals/pediatrics/articles/10.3389/fped.2025.1630157/full

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

Friedlander JA, Smith C, Nguyen N, et al. JPGN 2024, E-Pub

This case report investigates the feasibility of Functional Endoscopic Esophageal Evaluation of Swallowing (FEEES) using unsedated TNE, particularly focusing on its application in a 14-year-old male diagnosed with Type 2 Achalasia and Eosinophilic Esophagitis (EoE).

https://onlinelibrary.wiley.com/doi/10.1002/jpn3.12154

Featured Literature Highlighting EvoEndo

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

Friedlander JA, Leinwand K, Bhardwaj V, Nguyen N

Front Pediatrics. 2024 Jan 16;11:1267148

This study provides a comprehensive guide for establishing a pediatric sedation-free endoscopy program, to address the growing interest in TNE within the pediatric gastroenterology community.

https://www.frontiersin.org/articles/10.3389/fped.2023.1267148/full

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