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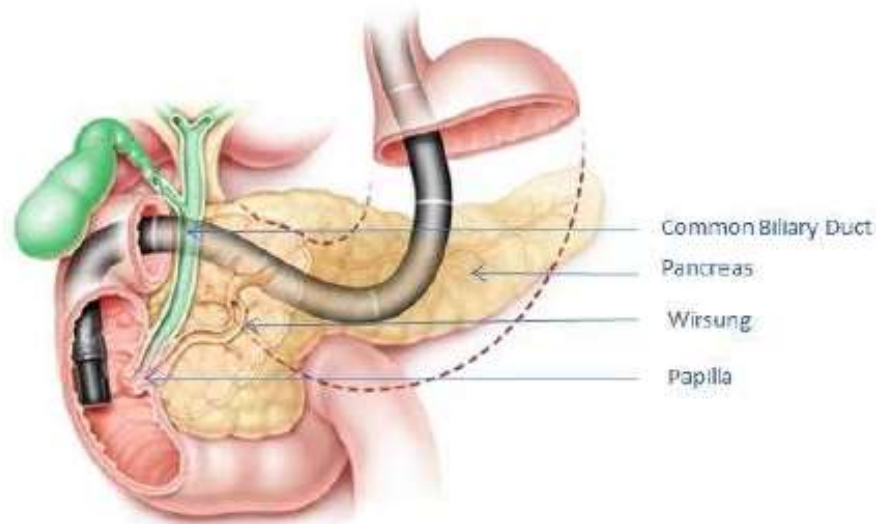
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ICD-10-PCS Code Request for EXALT™ Model D Single-Use Duodenoscope

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Endoscopic Retrograde Cholangiopancreatography Procedural Background

- Endoscopic Retrograde Cholangiopancreatography (ERCP) is a complex procedure used to diagnose and treat diseases, tumors, and cancers of the pancreaticobiliary system.
- Approximately 700,000 ERCP procedures are performed annually in the U.S. in both the inpatient and outpatient hospital settings of care.¹



ERCP Used to Diagnose and Treat Many Diseases

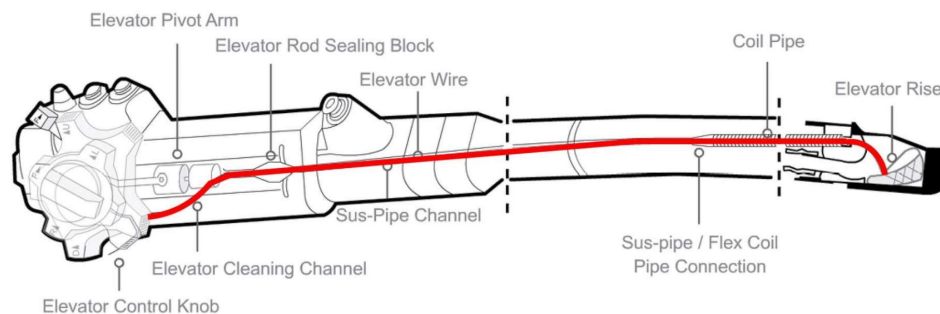
- Biliary tract cancer
- Pancreatic cancer
- Intraductal papillary mucinous neoplasms of the pancreas
- Choledocholithiasis
- Primary sclerosing cholangitis
- Pancreatitis
- Pancreatic strictures / masses
- Pancreatic stones / debris
- Pancreatic leaks or fistulas
- Biliary strictures / masses

ERCP Procedural Steps

- Physician inserts a duodenoscope through the patient's mouth, down the esophagus, into the stomach, and into the first part of the small intestine (duodenum).
- Next, a cannula is passed through the duodenoscope via a working channel and used to cannulate a small opening in the duodenal wall.
- Contrast is injected and x-rays are taken to study the bile and/or pancreatic ducts.
- If the physician identifies an area that warrants further investigation, accessory devices can be inserted through the working channel of the duodenoscope and into the pancreaticobiliary system for diagnosis or treatment.
- At the conclusion of the procedure, the duodenoscope is removed.

Challenges with Technology

- ERCP has historically been performed using a reprocessed duodenoscope, a complex endoscope with small working channels that is intrinsically challenging to disinfect.^{2,3}

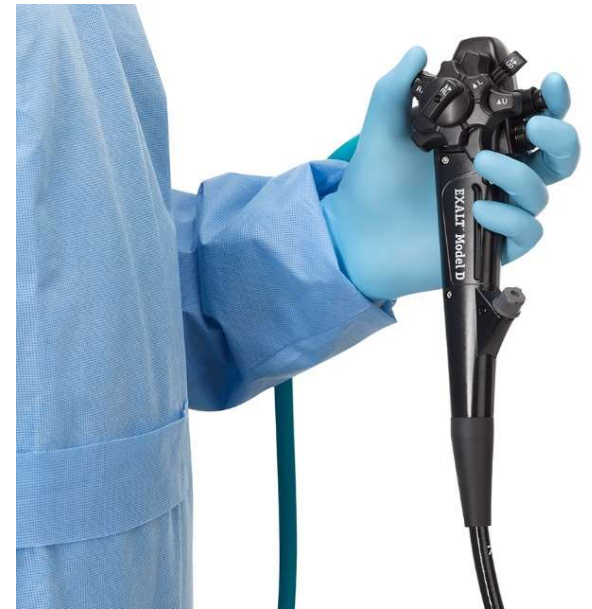


- FDA Safety Communication recommends transition to disposable devices, including disposable duodenoscopes (August 2019).⁴
- Recent results from an FDA mandated study of reprocessed duodenoscopes have demonstrated a high contamination rate of 5.0%.^{5,6}

EXALT™ Model D Single-Use Duodenoscope

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- Boston Scientific has developed the first single-use duodenoscope, EXALT Model D, eliminating risk of patient-to-patient transmitted disease caused by contaminated reprocessed duodenoscopes.
- The EXALT Model D is designed to function similarly to reusable duodenoscopes.
- EXALT Model D has received FDA Breakthrough Device Designation and is commercially available for sale.



- A consecutive case series of 60 ERCPs utilizing EXALT Model D was completed across 6 U.S. academic medical centers.⁷
- Indications included pancreaticobiliary stone clearance, stent placement, exchange and/or removal and balloon dilation.
- Adverse events:
 - 3 patients developed post-ERCP pancreatitis
 - 1 patient had post-sphincterotomy bleeding
 - 1 patient had worsening of a preexisting infection and required rehospitalization

No Unique ICD-10-PCS Established

Existing ERCP ICD-10-PCS codes do not uniquely identify the use of a single-use duodenoscope, and do not allow for accurate reporting and outcomes-tracking when utilizing this device.

Thank you!

References

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