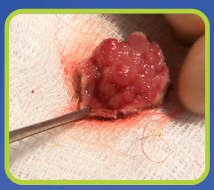
GelPOINT® Path

TRANSANAL ACCESS PLATFORM

PROCEDURAL GUIDE FOR TRANSANAL MINIMALLY INVASIVE SURGERY (TAMIS)



Featuring Tips & Tricks from Dr. Matthew Albert, Florida Hospital

Applied Medical

A New Generation Medical Device Company

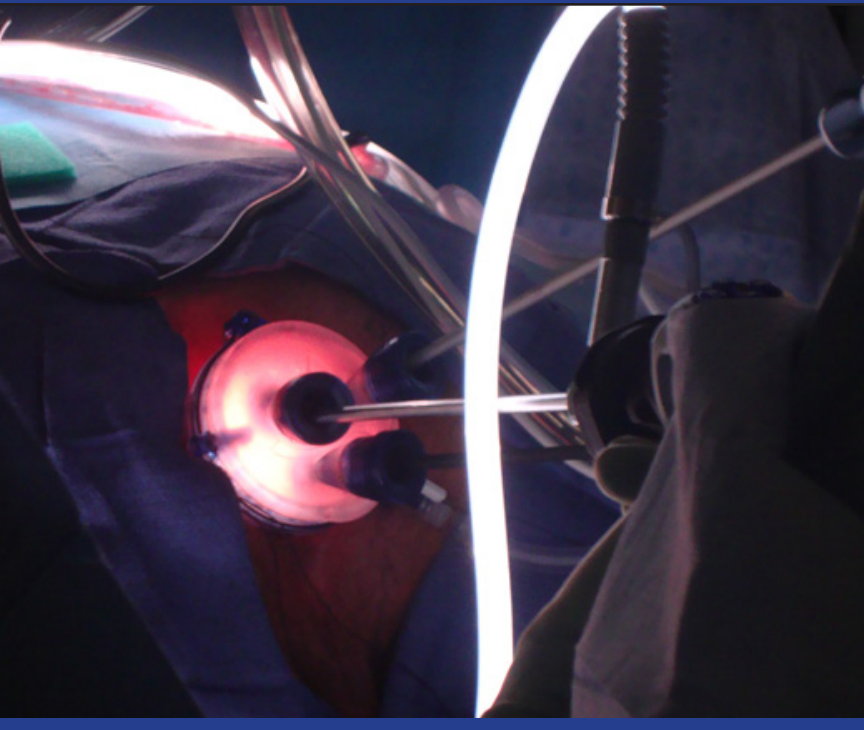
TAMIS is designed to resect benign polyps and well selected malignancies in the distal and mid-rectum using new advanced access platforms combined with standard laparoscopic instrumentation.

In collaboration with Dr. Matthew Albert and other leading surgeons, Applied Medical is pleased to offer TAMIS workshops using the GelPOINT® path transanal access platform. Based on materials from these workshops, this quick reference guide was created to give you an overview of the surgical techniques using TAMIS. As this guide is just a summary of some key points from the workshops, Applied Medical recommends all surgeons be adequately trained at a TAMIS workshop before performing this technique.

Any content and views expressed herein are those of Dr. Albert and not of Applied Medical.

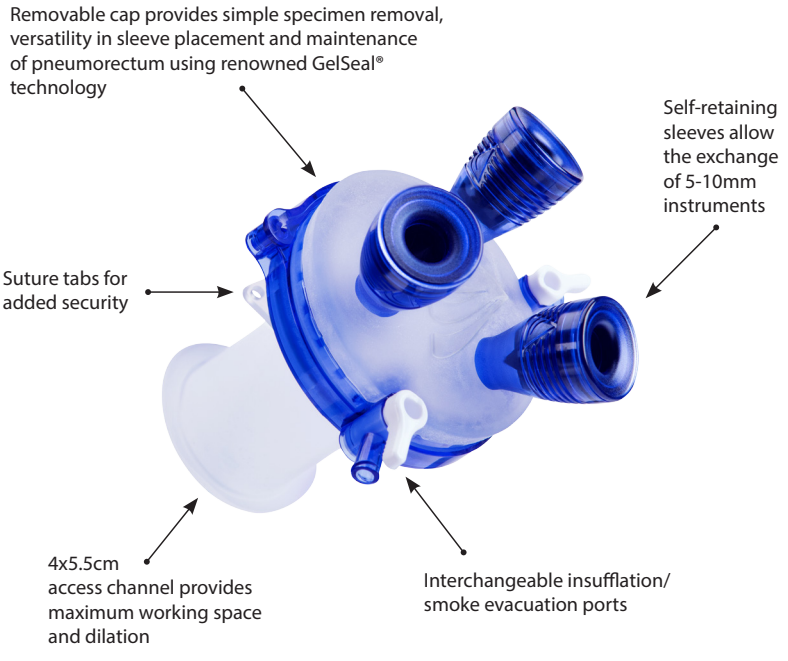
TAMIS OVERVIEW

The GelPOINT path transanal access platform is indicated for multiple instrument or camera access through the anus for the performance of various diagnostic and therapeutic procedures using additional instruments.



INDICATIONS

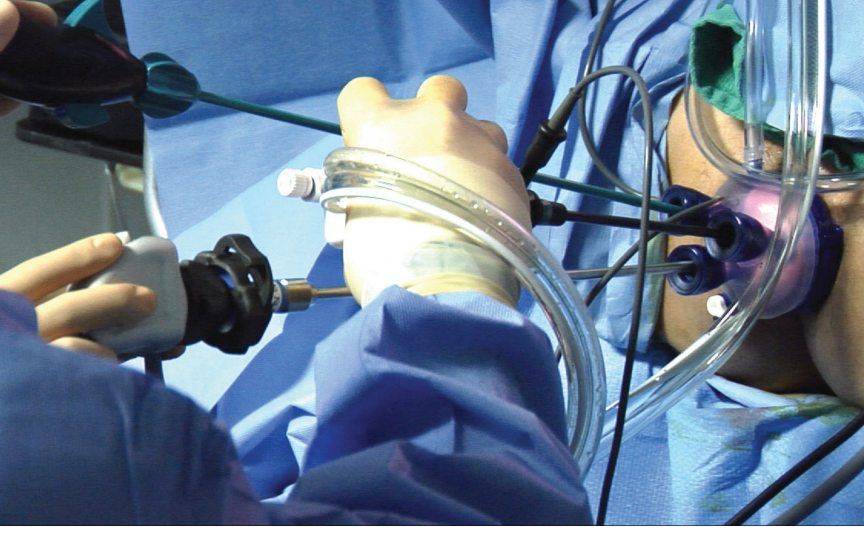
GelPOINT Path
TRANSANAL ACCESS PLATFORM



Model Number	Description	Size	Quantity
CNO11	GelPOINT Path	4cm x 5.5cm	1/BOX

GelPOINT Path Components		
GelSeal Cap	7.5cm diameter	1
Access Channel with Introducer	4cm x 5.5cm	1
Self-Retaining Sleeves	10mm	4
Obturator	10mm	1

PRODUCT SPECIFICATIONS

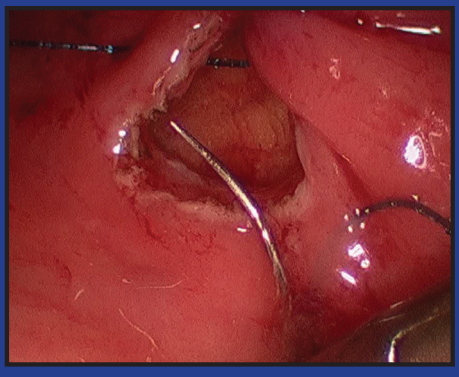


LAPAROSCOPE

- 5 or 10 mm/30° or 45° angled laparoscope
- Angled light cord adaptor
- Straight or specialized transanal instruments
  - Appropriate bowel graspers, scissors, needle driver

ENERGY DEVICES

- Monopolar cautery
  - L-Hook or pin-point
  - Combined suction/irrigation/cautery devices
- Bipolar energy devices
  - Can be beneficial early in a surgeon's experience, during bleeding, or for high lesions



SUTURE

- Absorbable suture
- Ethicon 3-0 PDS™ sutures, VICRYL™ sutures
- Covidien V-Loc™ or Surgical Specialties Quill™ suture

SUTURING DEVICES

Intracorporeal

- Covidien Endo Stitch™ suturing device
- LSI RD180™ Running Device

Knot Tying

- Ethicon LAPRA-TY™ suture applier
- LSI TK Ti-KNOT™ device
- Richard Wolf TEM suture clips

Extracorporeal knot tying

- Laparoscopic knot pusher

PREOPERATIVE PREPARATIONS

- Complete mechanical bowel preparation
- Preoperative antibiotics per Surgical Care Improvement Project (SCIP)
  - Cefotan 2g, Metronidazole 500mg
  - Invanz 1g (IV)
- Perianal skin preparation and sterile draping per standard proctologic surgery protocol

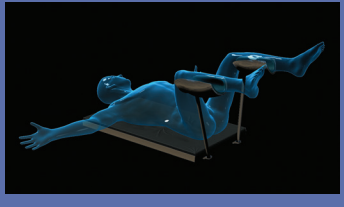
ANESTHESIA

- General endotracheal anesthesia per standard OR/ anesthesiology guidelines
  - Optimal rectal distention is obtained in a paralyzed patient in mild/moderate Trendelenburg position
  - TAMIS under spinal anesthesia* has been safely performed in a series of patients, and can be considered depending on ASA class.

* Taek-Gu L, Sang-Jeon, L. Transanal single-port microsursurgery for rectal tumors: minimal invasive surgery under spinal anesthesia. Surg Endosc. 2014; 28: 271-280.

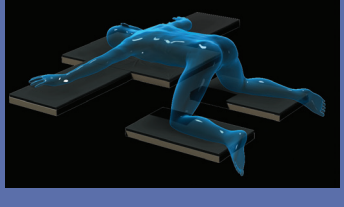
Unlike traditional TEM procedures, TAMIS procedures do not require positioning based on tumor location. However, the following are some recommendations on patient positioning and their potential benefits.

TRADITIONAL LITHOTOMY POSITION



- Facilitates comfortable sitting position for the surgeon
- Most advantageous for anesthesiologist
- Legs should be abducted and flexed past 90 degrees at the hips to provide optimal exposure of the perianal region and create sufficient space for instrument manipulation

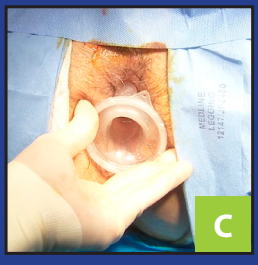
MODIFIED PRONE POSITION



- May be helpful for anterior lesions
- Degree of upper-body downward tilt depends on patient's body habitus and circulatory status
- Legs should be abducted and flexed at the hips

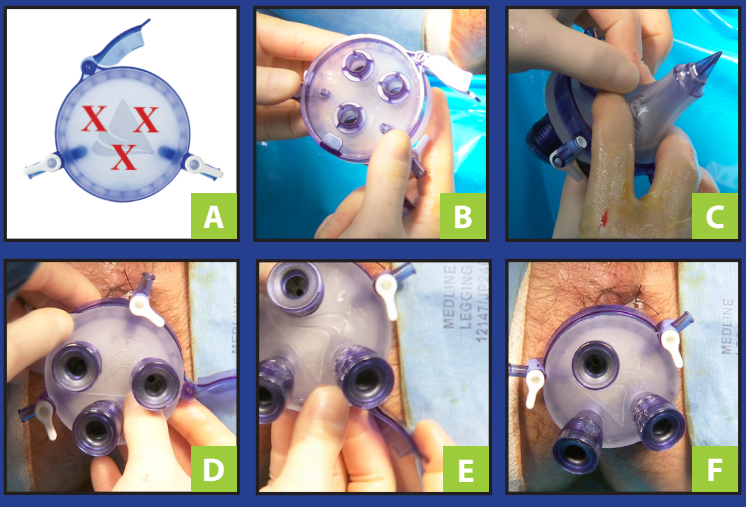
RIGHT OR LEFT LATERAL DECUBITUS POSITION

- May be advantageous for obese patients to facilitate pneumorectum
- Legs should be abducted and flexed at the hips, upper leg is secured to contoured rest on anterior side of table while lower leg is placed on leg rest of table and angled forward beneath the hip



1. Apply generous lubrication to access channel and introducer. Pre-dilate the anus using standard transanal surgery techniques.
2. Manually (A) or using forceps (B), compress access channel in a folded form and place into anus until flange is securely seated behind levator sling (C).
3. Introducer may be inserted to aid in placing the access channel into position (D).
4. Hold access channel in place while suturing through suture tabs to secure (E).
5. Access channel is now fully placed (F).

STEPS: INSERTING THE ACCESS CHANNEL

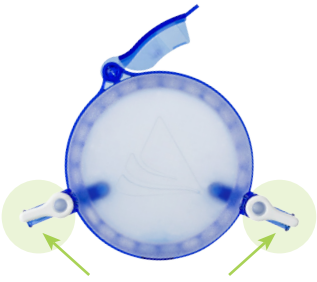


CAUTION:

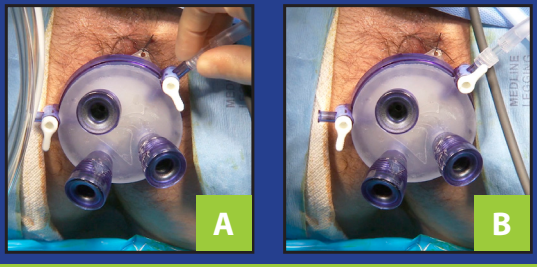
TO AVOID POSSIBLE INJURY TO RECTAL WALL, INSERT TROCARS INTO GelSeal CAP PRIOR TO PLACING GelSeal CAP ONTO ACCESS CHANNEL.

1. Using the 10mm obturator, place the 10mm sleeves, in a triangular fashion (A), see red X for position, through the gel in the GelSeal cap. Ensure sleeves are at least 1cm from the cap's plastic perimeter and the insufflation and smoke evacuation ports (B).
2. Apply downward force to the sleeve until the sleeve tip and flange have passed through the GelSeal cap (C). Remove obturator.
3. Attach the GelSeal cap to the access channel by sliding the blue tab located on the bottom of the GelSeal cap under the access channel's upper ring (D).
4. Push the upper ring against the inner portion of the GelSeal cap. Secure the opposite side of the access channel by closing the lever and locking the GelSeal cap in place (E).
5. Cap is now fully attached and ready for use (F).

STEPS: INSERTING TROCARS & ATTACHING CAP



INTERCHANGEABLE INSUFFLATION/ SMOKE EVACUATION PORTS

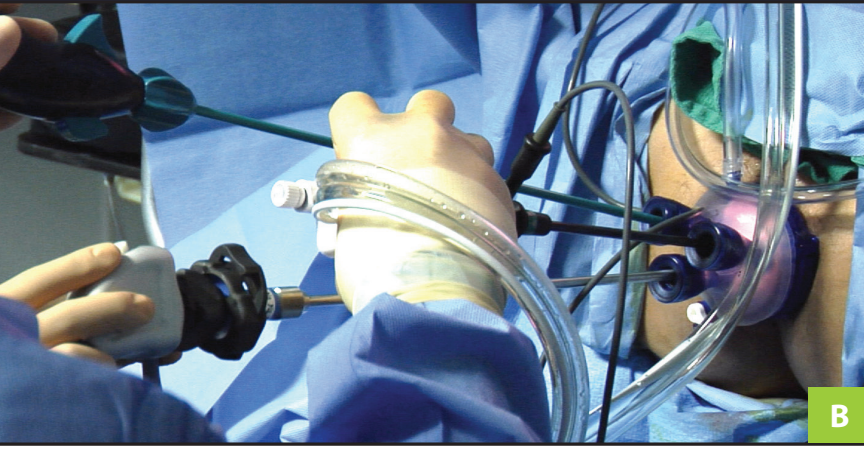


NOTE:

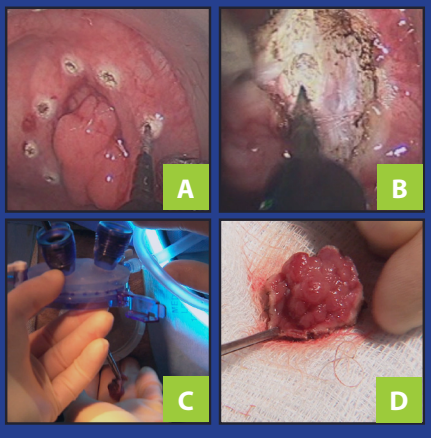
ATTACH INSUFFLATION TUBING ON EITHER STOPCOCK PORT. REMAINING PORT IS DESIGNATED FOR SMOKE EVACUATION.

1. Attach insufflation tubing to either one of the stopcock ports located on the GelSeal cap (A).
2. With high flow setting, start pressure at 8mmHg and increase to 15-20mmHg as needed for desired rectal distention.
3. If rectum pulsates or collapses:
   - Close smoke evacuation port
   - Increase pressure in 1-2mm increments
   - Confirm GelSeal cap is secured to access channel
   - Confirm intact seals in all trocar ports
   - Minimize suctioning of smoke to short bursts
4. To evacuate smoke during the procedure, move the stopcock valve on the designated smoke evacuation port to the open position. After smoke evacuation, move the stopcock valve to the closed position (B).

STEPS: INSUFFLATION/SMOKE EVACUATION



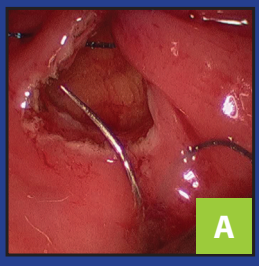
- Posterior lesion
  - Camera at top of triangle (A)
- Anterior lesion
  - Camera at bottom of triangle (B)
- Angle the scope to be out of your way!
- Bariatric length scopes and port changes may be helpful.

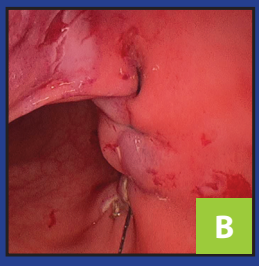


NOTE :
INITIAL EPINEPHRINE INJECTION BEFORE START OF CASE CAN LIFT LESION TO FACILITATE SUBMUCOSAL DISSECTION AND MINIMIZE BLEEDING FROM MURAL VESSELS.

1. Mark out resection plane with series of coagulation points with monopoloar electrode around the tumor (A).
   - Maintain a 5-10mm safety margin when marking out the lesion.
   - A slightly wider margin distally can allow easy grasping of the bowel wall without tumor manipulation.
   - Confirm sufficient access to all portions of the lesion, including those behind a valve or extending more proximally.
2. The dissection is initiated distal to the lesion with a full thickness incision of the rectal wall entering the areolar tissue between the muscularis and perirectal fat.
   - Grasping the distal bowel wall with traction proximally allows initial posterior dissection (B).
   - The rectal wall is divided along the previously cauterized margins confirming the proximal extent of the lesion.
   - For lesions that extend below the access channel, an initial proctotomy can be performed utilizing a rectal retractor.
   - Pneumodissection is maximized when performing full thickness resections.
   - Perforating vessels from the mesorectum into the rectal wall require appropriate hemostasis.
3. Remove specimen as soon as excised (C).
   - Avoids proximal migration
   - Allows for immediate inspection of margins (D)

STEPS: SPECIMEN EXCISION





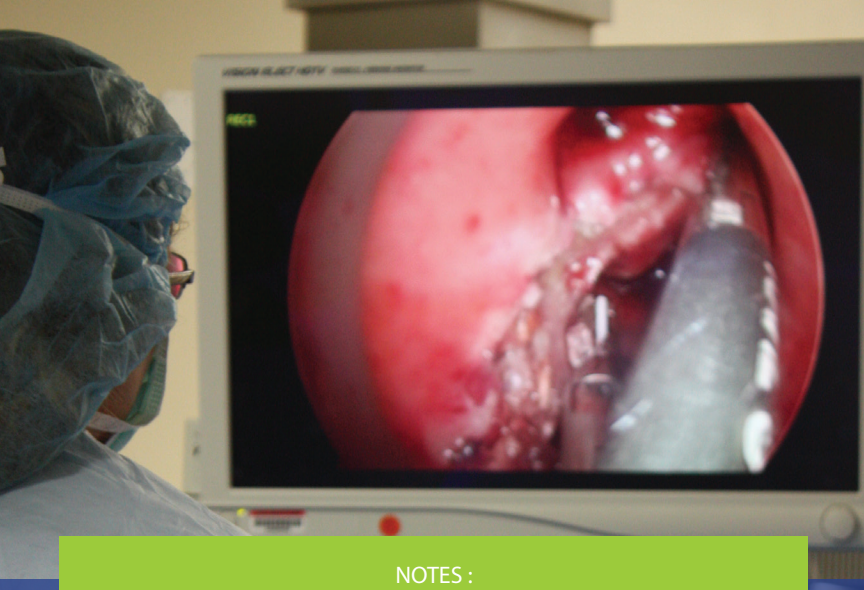
NOTES :

THE GOAL IS TO FULLY REAPPROXIMATE THE BOWEL WALL WITHOUT NARROWING THE LUMEN. IF DEFECT IS VERY DISTAL MAY REMOVE GelPOINT PATH AND CLOSE TRANSANALLY.

ENTRY INTO PERITONEAL CAVITY:
RESECTION OF ANTERIOR LESIONS LOCATED 6CM AND PROXIMAL TO THE ANAL VERGE HAVE THE POTENTIAL FOR PERITONEAL ENTRY DURING FULL THICKNESS EXCISION, REQUIRING SUTURE CLOSURE OF THE PERITONEUM AND RECTAL WALL.

- Irrigation of the rectal defect is traditionally performed prior to closure with dilute betadine.
- Lowering insufflation pressure will help reapproximate a larger defect.
- The rectal wall defect may be closed with standard laparoscopic needle holders and suture, or using preferred suturing devices up to 10mm.
- Large rectal wall defects can be divided into 2 smaller wounds facilitating closure alignment, with an initial suture in the midline of the defect.
- Fully closed defect (B)
- Monofilament absorbable suture
  - Continuous or interrupted
  - 3-0 PDS sutures, VICRYL sutures
  - Covidien V-Loc™ barbed sutures or Surgical Specialties Quill™ barbed suture may facilitate suture retention

STEPS: SUTURING/DEFECT CLOSURE



NOTES :

OCCASIONAL VESSELS MAY BE ENCOUNTERED IN THE DISSECTION THROUGH THE RECTAL WALL AND MESORECTUM CAUSING SUDDEN BLEEDING.

WHEN BLEEDING DOES OCCUR REMEMBER THE FOLLOWING:

- Don't panic!
- Maintain visualization (use short bursts of suction with minimal irrigation).
- Attempt compression with grasper prior to blind electrocautery.
- Utilization of an advanced energy device may quickly resolve the problem.

Tip: Initial epinephrine injection at start of case can lift lesion to aid in dissection and minimize major vessel bleeding.

EARLY POSTOPERATIVE CARE

- Resumption of regular diet per standard protocol
- Discharge may be within 24 hours
- Contrast enema on postoperative day ONE if intraperitoneal entry was made during procedure

ONCOLOGIC FOLLOW-UP

- Follow standard recommendations of the professional societies and NCCN guidelines.
- If postoperative histology shows positive margins, poor pathologic features or more advanced tumor stage, standard oncologic resection or alternative treatment options should be considered.

GelPOINT Path Transanal Access Platform

The information contained in this document is provided for general coding example purposes only. The GelPOINT path transanal access platform is indicated for multiple instrument or camera access through the anus for the performance of various diagnostic and therapeutic procedures using additional instruments. The coding options listed below are only examples of surgical procedures that may use the GelPOINT path transanal access platform.

CODING EXAMPLES OF DIAGNOSES AND SURGERIES

CPT CODING		
CPT Code Examples	0184T*	Excision of rectal tumor, transanal endoscopic mircrosurgical approach (ie. TEMS) including muscularis propria (ie. full thickness)
	45171	Excision of rectal tumor, transanal approach; not including muscularis propria (ie. partial thickness)
	45172	Excision of rectal tumor, transanal approach; including muscularis propria (ie. full thickness)
ICD-9 CODE EXAMPLES		
ICD-9-CM DIAGNOSIS Code Examples	154.1	Malignant neoplasm of rectum
	209.17	Malignant carcinoid tumor of the rectum
	209.57	Benign carcinoid tumor of the rectum
	211.4	Benign neoplasm of rectum and anal canal
	230.4	Carcinoma in situ of rectum
ICD-9-CM PROCEDURE Code Examples	48.35	Local excision of rectal lesion or tissue

*CPT Code 0184T is considered a CPT Category III code

> "Codes within this category are temporary codes for emerging technology, services and procedures. Category III codes allow for the collection of specific data. If a Category III code is available, this code must be reported instead of a Category I unlisted code. This is an activity that is critically important in the evaluation of health care delivery and the formation of public and private policy. The use of the codes in this section allows physicians and other qualified health care professionals, insurers, health services researchers, and health policy experts to identify emerging technology, services, and procedures for clinical efficacy, utilization, and outcomes." (http://www.ama-assn.org/ama1/pub/upload/mm/362/cptcat3codes.pdf)

**All above referenced codes are examples only – code according to the patient's medical condition and procedure(s) performed.

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