

PROCEDURAL GUIDE FOR

TRANSANAL MINIMALLY INVASIVE SURGERY

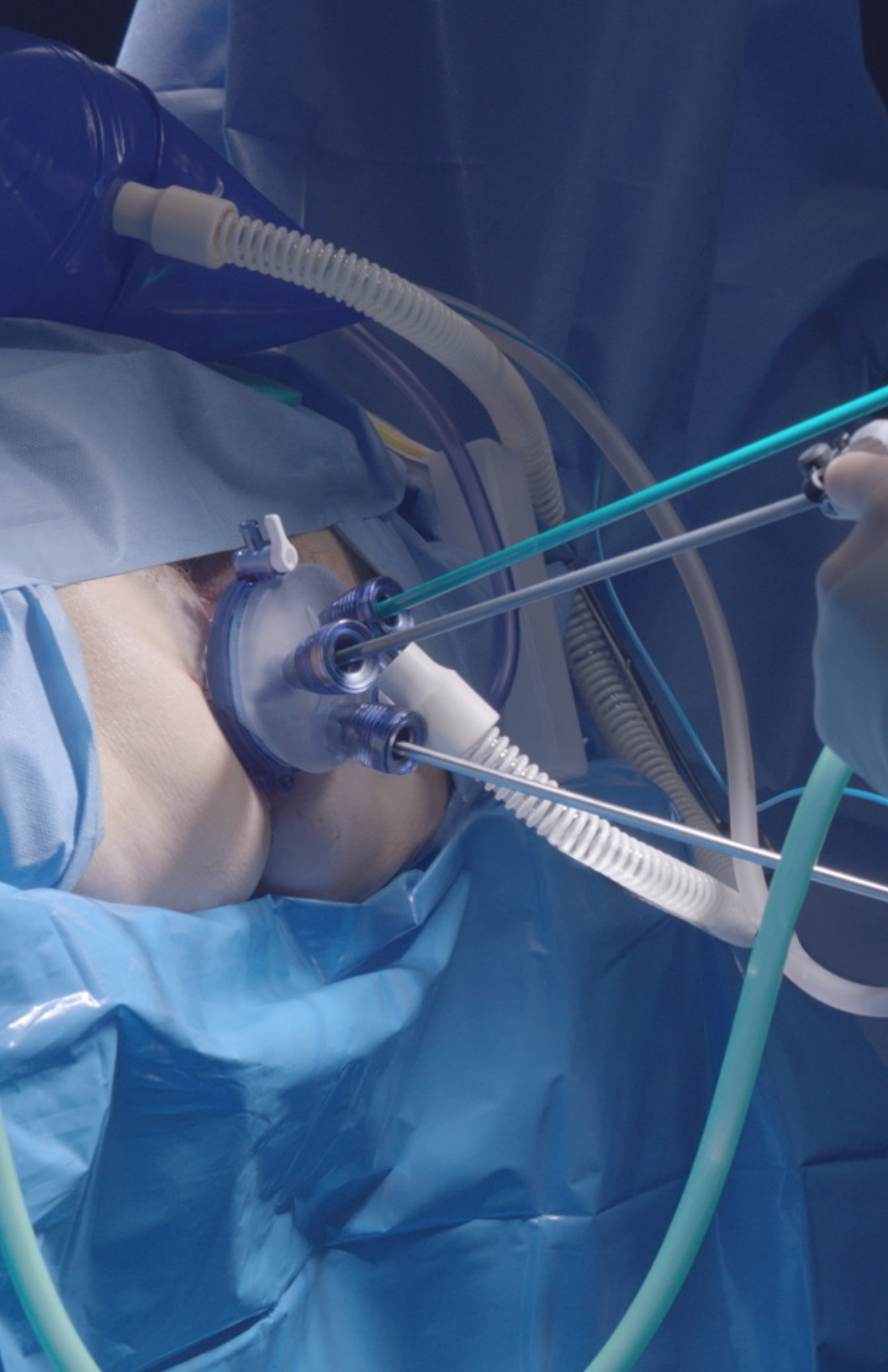
FEATURING TIPS AND TRICKS FROM
MATTHEW ALBERT, MD, FACS, FASCRS

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TAMIS Overview

Transanal Minimally Invasive Surgery (TAMIS) is performed to resect benign and malignant lesions in the distal to proximal rectum using transanal access platforms and standard laparoscopic instrumentation.

Applied Medical is pleased to collaborate with Dr. Matthew Albert and other leading surgeons to offer TAMIS workshops using the GelPOINT® Path transanal access platform. This reference guide intends to give you an overview of the surgical technique and materials used during TAMIS. Applied Medical recommends that all surgeons be adequately trained at a TAMIS workshop before performing the technique.

This guide serves as a summary of key points covered in the workshops. Any content and views expressed herein are those of Dr. Matthew Albert and not of Applied Medical.

Indications

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.

This information is not intended to replace the Instructions for Use (IFU). Please refer to the IFU for the indications, contraindications, warnings, precautions, instructions and other information.

Instrumentation

Laparoscope

- 5/10mm laparoscope with 30/45° angle
- Angled light cord adaptor

Instruments

- Straight or angled laparoscopic instruments
 - Bowel graspers, scissors, needle driver

Energy Devices

- Monopolar cautery
 - Epix electrosurgical probe with smoke evacuation
 - Combined suction/irrigation/cautery devices
- Bipolar energy devices
 - Can be beneficial early in a surgeon's experience, during bleeding, or for high lesions



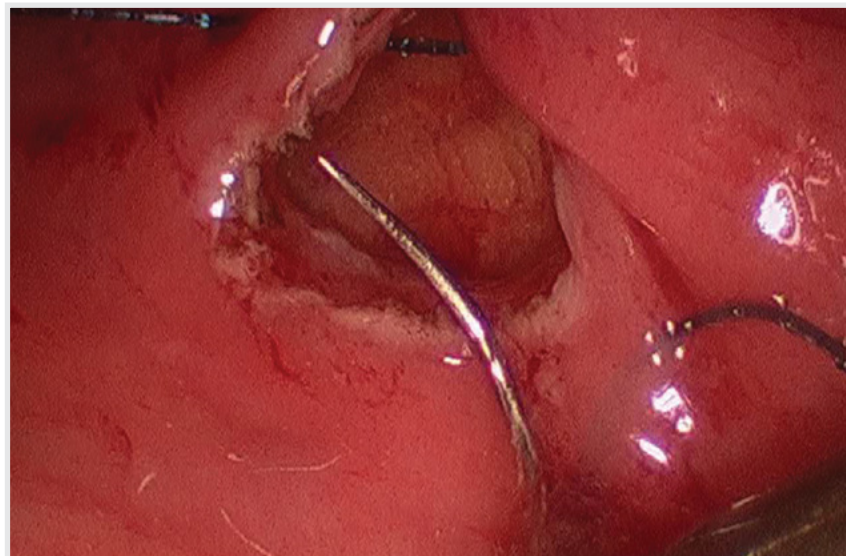
Suture/Suturing Devices

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 RD 180™ 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

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 microsurgery for rectal tumors: minimal invasive surgery under spinal anesthesia. Surg Endosc. 2014; 28: 271-280.

Patient Positioning

TAMIS does not require positioning based on tumor location. The most commonly used patient position for TAMIS is Traditional Lithotomy, as shown below.



Traditional Lithotomy Position

Advantages: facilitates comfortable seated position for the surgeon. Provides optimal exposure of the perianal region, creating space for instrument manipulation. Most advantageous for the anesthesiologist.

Legs: should be abducted and flexed past 90° at the hips.

Note: degree of Trendelenburg depends on patient's body habitus and circulatory status.

If Traditional Lithotomy is not desired, the following positions may be used.



Modified Prone Position

Legs: should be abducted and flexed at the hips.

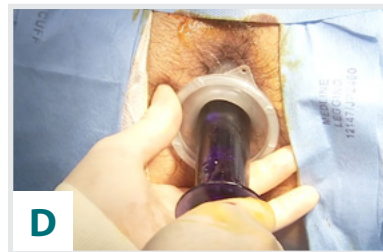
Note: degree of Trendelenburg depends on patient's body habitus and circulatory status.



Right or Left Lateral Decubitus Position

Legs: should be abducted and flexed at the hips; upper leg is secured to the anterior side of the table while lower leg is placed on leg rest of table.

Inserting the Access Channel

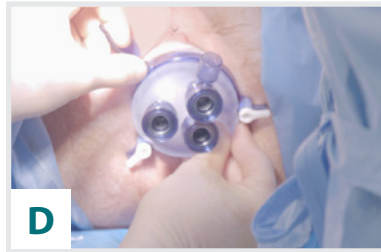
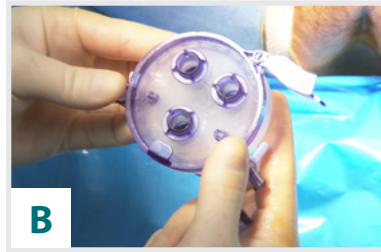
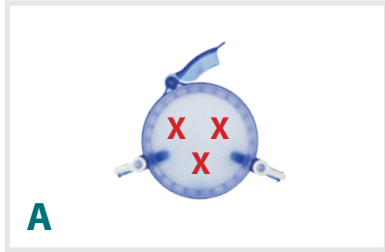


1. Apply generous lubrication to access channel and introducer. Pre-dilate the anus using standard transanal surgery techniques.
2. Manually (A) or using forceps (B), compress access channel in a folded form and place into anus until flange is securely seated behind levator sling (C).
3. Introducer may 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).

Access Channel Recommendations

Access Channel Size	Suggested Usage
5.5cm	Suitable for most patients
4cm	Suitable for patients with a shorter anal canal and/or distal lesions
9cm	Suitable for patients with a longer anal canal and/or proximal lesions

Inserting Trocars and Attaching Cap



1. Using the 10mm obturator, place the 10mm sleeves in a triangular fashion (A) through the GelSeal® cap. Ensure sleeves are at least 1.5cm from the cap perimeter and the stopcock valves (B).
2. Apply downward force to the sleeve until the sleeve tip and flange have passed through the GelSeal cap (C). Remove obturator.

CAUTION: To avoid possible injury to rectal wall, insert trocars into GelSeal Cap prior to placing GelSeal Cap onto access channel.

3. The ISB sleeve should be placed in the upper half of the GelSeal cap with the ISB sleeve inlet pointing toward the perimeter of the cap.
4. 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 outer ring (D). Ensure that the blue tab is not clashing with suture tabs.
5. Push the outer 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).
6. Cap is now fully attached.

NOTE

- If use of the ISB is not desired, three standard sleeves can be used.

Attaching the Insufflation Stabilization Bag (ISB)



1. Connect the ISB tubing to the ISB sleeve inlet (A).
2. Connect the insufflation tubing to the luer port on the opposite side of the ISB reservoir (B).
3. Drape the ISB tubing over the patient's leg or place the ISB reservoir on the patient's abdomen (C).
4. Before insufflation, ensure both stopcock valves are in the closed position.
5. Once both stopcock valves are closed, insufflation may be established in accordance with standard surgical protocols.

NOTE

- If use of the ISB is not desired, attach insufflation tubing directly to a stopcock valve on the GelSeal cap.
- The Epix electrosurgical probe may be used to evacuate smoke during a procedure. If use of this device is not desired, smoke may be evacuated by moving one stopcock to the open position or connecting a smoke evacuation system to one stopcock valve.

Setting up the Epix Electrosurgical Probe with Smoke Evacuation

1. Remove the tip protector and paper sleeve. Take care to keep the entire device within the sterile field when opening.
2. Attach tubing to a suction canister. While the device is only intended for the removal of smoke, it is recommended to attach it to a suction canister in case of accidental aspiration of liquids or solids.
3. Connect the device to a monopolar generator. The opening at the base of the handpiece accommodates standard 4mm monopolar connectors.

NOTE

- It is recommended to confirm compatibility between available cables and the device handpiece before use.

Using the Epix Electrosurgical Probe with Smoke Evacuation

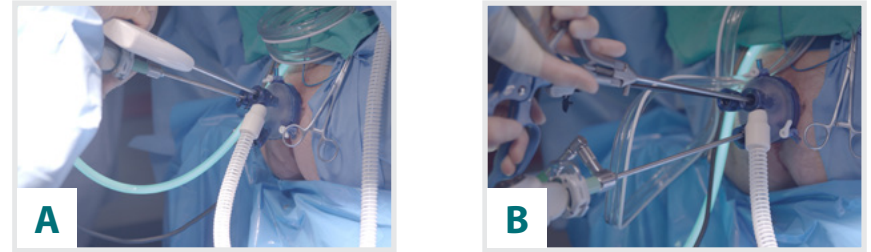


1. Extend the sheath before inserting the device through a GelPOINT sleeve or Kii® trocar. The sheath should stop when the slider reaches a notch at the recommended extended position (A).
2. Retract the sheath before using monopolar energy. The sheath should stop when the slider reaches a notch at the recommended retracted position (B).
3. Activate smoke evacuation by pressing the button on the device handpiece. The smoke evacuation rate will increase the further the button is pressed.
4. Extend the sheath before removing the device from a GelPOINT sleeve or trocar.

NOTE

- Angled configurations of the Epix electrosurgical probes are compatible with Applied Medical GelPOINT sleeves and Applied Medical Kii 12x60-100mm and 15x100-150mm trocars.

Camera Driving



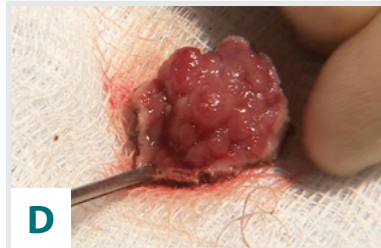
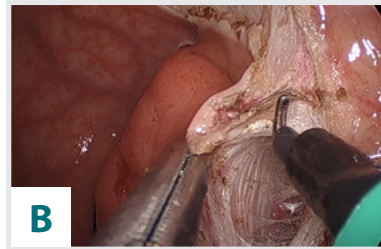
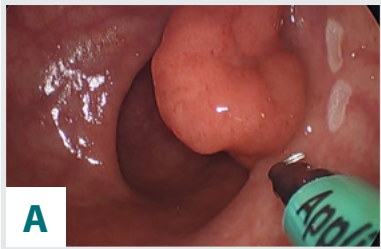
Posterior lesion: Camera on top (A)

Anterior lesion: Camera on bottom (B)

NOTE

- Angle the scope to be out of your way.
- Bariatric length scopes and port changes may be helpful.

Specimen Excision



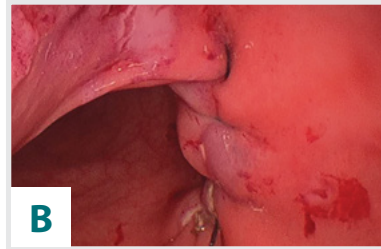
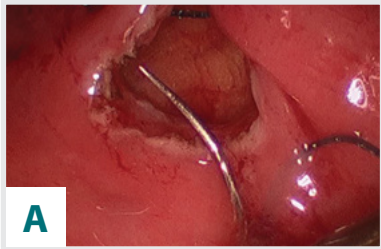
1. Use a monopolar electrode to mark out a resection plane around the lesion with a series of coagulation points (A).
 - Maintain a 5-10mm safety margin when marking out the lesion.
 - A slightly wider margin distally can allow easy grasping of the rectal wall without lesion manipulation.
 - Confirm 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.
 - Create traction by grasping the distal rectal wall and pushing proximally to allow initial posterior dissection (B).
 - Divide the rectal wall along the previously cauterized margins and confirm the proximal extent of the lesion.
 - If the lesion is low and is covered by the access channel, an initial proctotomy using a rectal retractor can be performed.
 - Pneumodissection is maximized when performing full thickness resections.
3. Remove specimen immediately after excision (C).
 - Avoids migration.
 - Allows for immediate inspection of margins (D).

NOTE

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

Suturing and Defect Closure



Suturing the Defect

- Irrigation of the rectal defect is traditionally performed prior to closure with dilute betadine.
- Lowering the 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 (A).
 - Fully closed defect (B).
- Large rectal wall defects can be divided into two smaller wounds facilitating closure alignment, with an initial suture in the midline of the defect.
- Monofilament absorbable suture may be used to close the rectal wall defect.
 - Continuous or interrupted
 - 3-0 PDS sutures, VICRYL sutures
 - Covidien V-Loc™ barbed sutures or Surgical Specialties Quill™ barbed sutures may facilitate suture retention

Peritoneal Entry

- Resection of anterior lesions located 6cm and proximal to the anal verge have the potential for peritoneal entry during full thickness excision, requiring closure of the peritoneum and rectal wall.

NOTE

- The goal is to fully reapproximate the bowel wall without narrowing the lumen. If the defect is very distal, the surgeon may remove the access channel and close transanally.

Hemostasis

When bleeding occurs 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.

NOTE

- Vessels may be encountered during dissection through the rectal wall and mesorectum causing sudden bleeding.
- Initial epinephrine injection at start of case can lift lesion to aid in dissection and minimize major vessel bleeding.



Postoperative Care

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.
- Standard oncologic resection or alternative treatment options should be considered if postoperative histology shows positive margins, poor pathologic features, or more advanced tumor stage.



Hospital Coding Examples

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 microsurgical approach (ie. TEMS) including muscularis propria (ie. full thickness)
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ICD-10 Code examples

ICD-10 CM Diagnosis code examples	C20	Malignant neoplasm of rectum
	C7A.026	Malignant carcinoid tumor of the rectum
	D3A.026	Benign carcinoid tumor of the rectum
	D12.7	Benign neoplasm of rectosigmoid junction
	D12.8	Benign neoplasm of rectum
	D12.9	Benign neoplasm of anus and anal canal
ICD-10 CM Procedure code examples	D01.1	Carcinoma in situ of rectosigmoid junction
	D01.2	Carcinoma in situ of rectum
	0DBP7ZZ	Excision of Rectum, Via Natural or Artificial Opening
	0DBP8ZZ	Excision of Rectum, Via Natural or Artificial Opening Endoscopic

*CPT Code 0184T is considered a CPT Category III code. CPT Code 45172 is not recommended for TAMIS coding as it excludes transanal endoscopic microsurgical tumor excision (TEMS)(0184T). For more guidance on TAMIS coding, please visit the American Society of Colon and Rectal Surgeons website at <https://www.fascrs.org/healthcare-economics-committee-resources>.

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

Reorder Information

GelPOINT Path Transanal Procedural Pack

Products are also available separately. Please see the following page for individual reorder information

Reorder No.	Qty/Box
TA211	1/Box

Components

- (1) GelPOINT Path transanal access platform, 4 x 5.5cm
- (1) Epix electro-surgical probe with smoke evacuation, angled L-hook tip



GelPOINT Path Transanal Access Platform with Insufflation Stabilization Bag

Reorder No.	Access Channel Size	Qty/Box
CNB10	4x4cm	1/Box
CNB11	4x5.5cm	1/Box
CNB12	4x9cm	1/Box

Components included in all above models

- (1) GelSeal Cap
- (1) Access Channel with Introducer
- (3) Sleeves
- (1) ISB Sleeve
- (1) Obturator
- (1) Insufflation stabilization bag (ISB)

Epix Electro-surgical Probe with Smoke Evacuation

Reorder No.	Tip Design	Size	Qty/Box
CW001*	Angled Spatula	5mm x 42cm	1/Box
CW002*	Angled L-Hook	5mm x 42cm	1/Box
CW003*	Angled Needle	5mm x 42cm	1/Box

Devices listed may not be approved in all markets. Please contact your Field Implementation team member for more information on availability.

*Angled configurations of the Epix electro-surgical probes are compatible with Applied Medical GelPOINT sleeves and Applied Medical Kii 12x60-100mm and 15x100-150mm trocars.

