EndoGastric Solutions®

Patient Management

Considerations for TIF® procedure

Surgical Goals of TIF

- **Principles of Traditional Anti-Reflux Surgery**

Elongate intra-abdominal esophageal segment

Reduce hiatal hernia (≤ 2 cm) if present

- if HH > 2cm, reduce with lap HHR prior to TIF

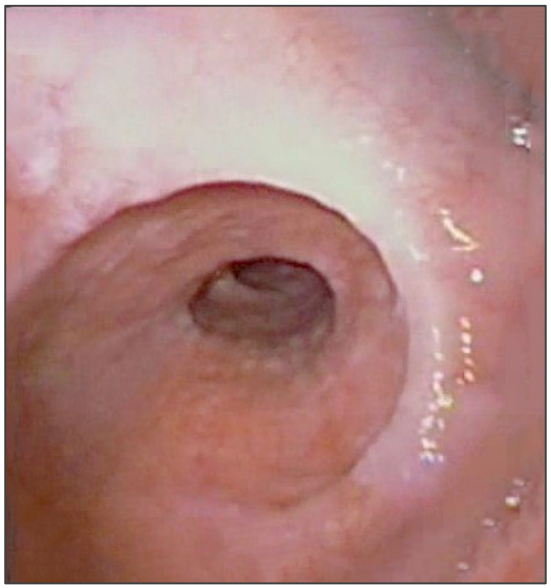
Create ≥270º wrap, 3cm flap valve

Recreate dynamics of angle of His

Restore high pressure zone (HPZ)

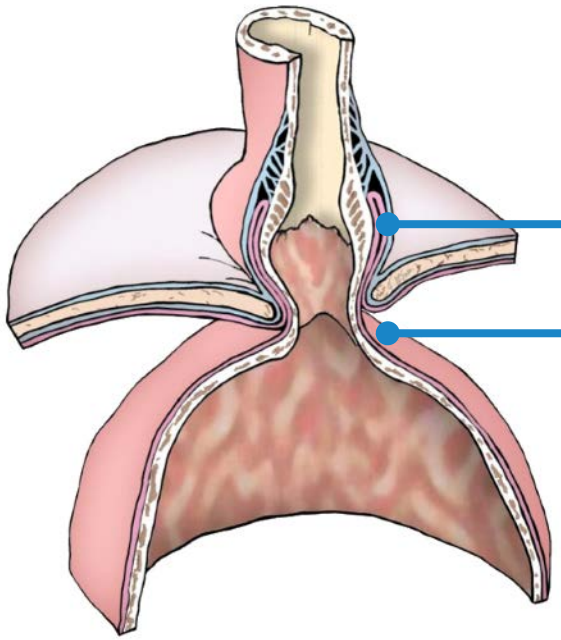
Pre-Operative EGD

- **Documentation during EGD**
- *(Always confirm endoscope compatibility with the EGS scope sizing tool prior to each procedure)*
- Examine esophagus for pathology, stricture or ulceration
- Determine the level of the GEJ and diaphragmatic pinch relative to the bite block measured using the markings on the endoscope shaft
- NPO compliance
- Assessment of Hill Grade
- Determine absence or presence (and size) of hiatal hernia
- Evaluate stomach volume for ease of Tissue Mold manipulation



Pre-Operative EGD

Determining the axial dimension of a hiatal hernia



- GEJ Measurement
- Diaphragmatic Pinch Measurement

Axial height of Hiatal Hernia

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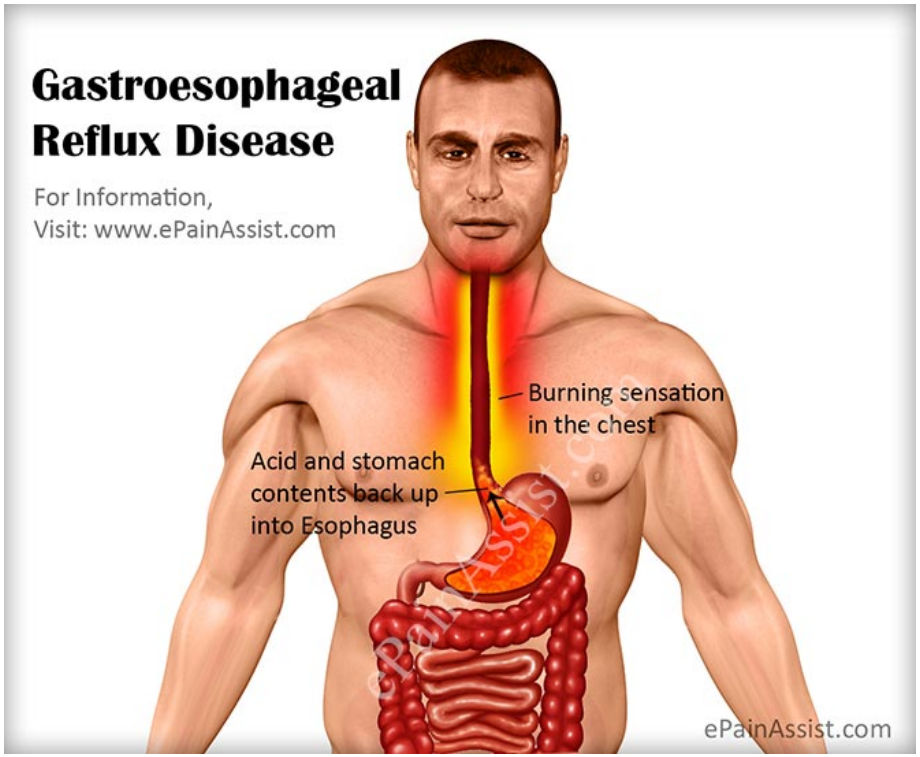
TIF® procedure: Transoral Incisionless Fundoplication

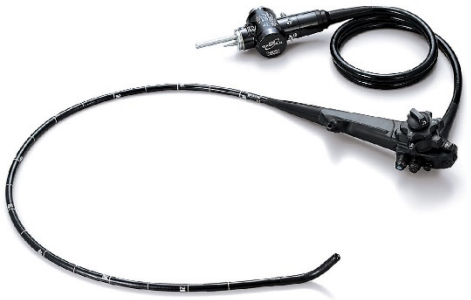
- Define our goal: Eliminate troublesome gastroesophageal reflux (GERD) in well-selected patient populations.
- Pre-op, Intra-op, Post-op
  - Evaluation
  - Expectations
  - Education



Evaluation

Select patient population – How do we know we have the correct patient for the TIF procedure?

- EGD
- Barium swallow
- Bravo pH monitor
- Esophageal manometry/motility
- Impedance
- HRQL
- Patient History/Complaint

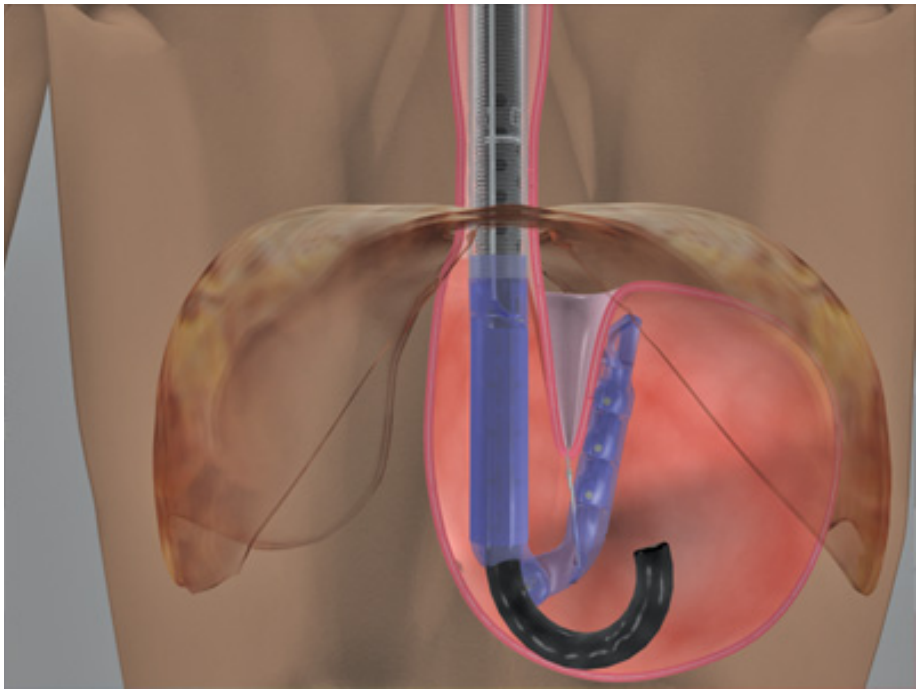


Select Patient Population

- Chronic GERD with partial but inadequate symptom control on high-dose PPI therapy
- Axial hiatal hernia ≤2cm, (must be re-ducible)
- Transverse hiatus ≤2cm
- Effective esophageal motility
- Esophagitis – A or B
- Hill Grade I or II
- Exclude
  - BMI >35
  - Barretts esophagus
  - Achalasia
  - Gastroparesis
  - Eosinophillic esophagitis
  - Erosive esophagitis - C or D
  - Hill Grade III or IV

Expectations

- Anesthesia
  - General, Full muscle relaxation (smooth muscle – diaphragm)
- Procedure
  - Device & Endoscope operators
  - Left lateral
  - Use bean bag or pillows for stabilization of patient and observe for pressure points
  - Secondary insufflation (CO2)
  - Back-up endoscope and devices availability
  - Injectable needles available



Expectations

- Medications
  - Antibiotics, Analgesics, Anti-emetics, Anti-gas, PPI's
  - Write post-op prescriptions including:
    - Analgesic for moderate to severe pain
    - Anti-emetic to control nausea and vomiting
    - Anti-gas agent to relieve bloating and discomfort
    - Laxative
    - PPI's

- Diet
  - Two week liquid with soft diet followed by four week progressive diet.
  - Slowly allow patient to return to regular meals. Physician may choose to give IV fluids for homeostasis and post-op nutrition.

Expectations

- Activity
  - Week 1: Short distance walking encouraged, minimal physical activity, no lifting > 5lbs
  - Week 2: Slow climbing stairs allowed, no intense exercise, no lifting > 5 lbs., sex allowed
  - Week 3-6: No intense exercise, may lift up to 25lbs.
  - Week 7: Resume normal activity
- Follow-up
  - 1-2 weeks post op
  - 3 months
  - If study, 6-9 months

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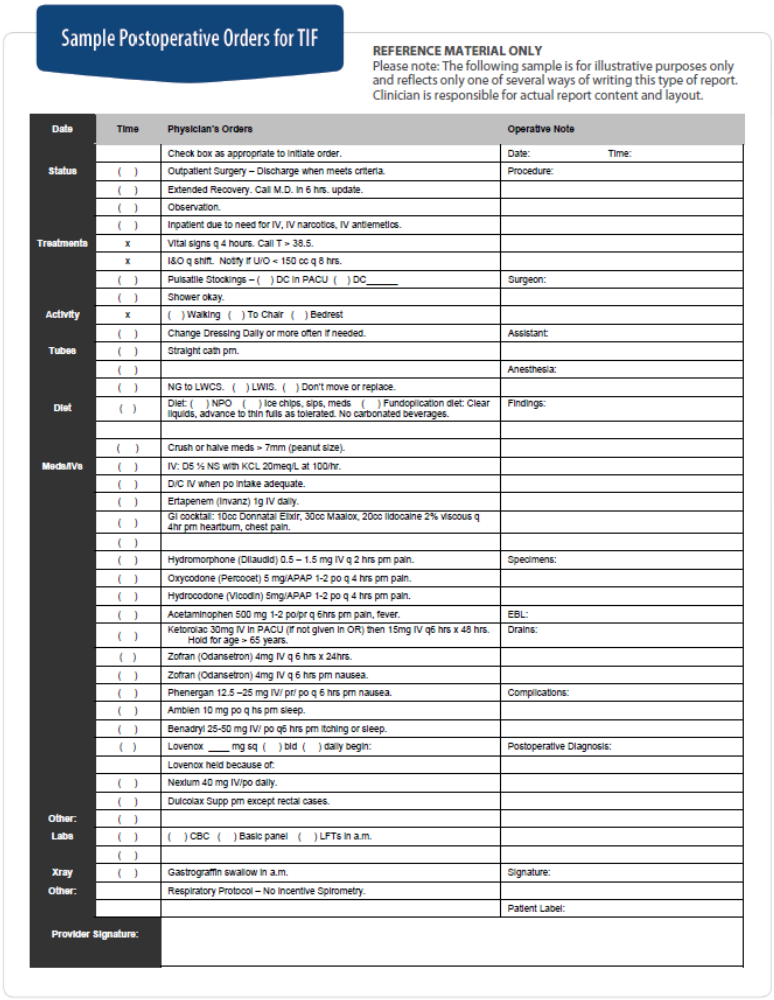
Educate

- PACU, Floor Staff, & Patient
  - No incisions, however, surgical procedure
  - Pre & Post-op orders standarized for expectations of care
  - Watch patient for the following and report to physician:
    - Tachycardia
    - Fever ≥ 101° F
    - Increasing chest pain
    - Light headedness/dizziness
    - Suspect pneumothorax
    - Melena
    - Patient not improving



Sample Postoperative Orders for TIF

REFERENCE MATERIAL ONLY
Please note: The following sample is for illustrative purposes only and reflects only one of several ways of writing this type of report. Clinician is responsible for actual report content and layout.

Date	Time	Physician's Orders	Operative Note
		Check box as appropriate to initiate order.	Date: Time:
Status	( )	Outpatient Surgery – Discharge when meets criteria.	Procedure:
	( )	Extended Recovery. Call M.D. in 6 hrs. update.	
	( )	Observation.	
	( )	Inpatient due to need for IV, IV narcotics, IV antiemetics.	
Treatments	x	Vital signs q 4 hours. Call T > 38.5.	
	x	I&O q shift. Notify if U/O < 150 cc q 8 hrs.	
	( )	Pulsatile Stockings – ( ) DC in PACU ( ) DC_____	Surgeon:
	( )	Shower okay.	
Activity	x	( ) Walking ( ) To Chair ( ) Bedrest	
	( )	Change Dressing Daily or more often if needed.	Assistant:
Tubes	( )	Straight cath pm.	
	( )		Anesthesia:
	( )	NG to LWCS. ( ) LWIS. ( ) Don't move or replace.	
Diet	( )	Diet: ( ) NPO ( ) Ice chips, sips, meds ( ) Fundoplication diet: Clear liquids, advance to thin fulls as tolerated. No carbonated beverages.	Findings:
	( )	Crush or halve meds > 7mm (peanut size).	
Meds/IVs	( )	IV: D5 ½ NS with KCL 20meq/L at 100/hr.	
	( )	D/C IV when po intake adequate.	
	( )	Ertapenem (Invanz) 1g IV daily.	
	( )	GI cocktail: 10cc Donnatal Elixir, 30cc Maalox, 20cc lidocaine 2% viscous q 4hr pm heartburn, chest pain.	
	( )		
	( )	Hydromorphone (Dilaudid) 0.5 – 1.5 mg IV q 2 hrs pm pain.	Specimens:
	( )	Oxycodone (Percocet) 5 mg/APAP 1-2 po q 4 hrs pm pain.	
	( )	Hydrocodone (Vicodin) 5mg/APAP 1-2 po q 4 hrs pm pain.	
	( )	Acetaminophen 500 mg 1-2 po/pr q 6hrs pm pain, fever.	EBL:
	( )	Ketorolac 30mg IV in PACU (if not given in OR) then 15mg IV q6 hrs x 48 hrs. Hold for age > 65 years.	Drains:
	( )	Zofran (Odansetron) 4mg IV q 6 hrs x 24hrs.	
	( )	Zofran (Odansetron) 4mg IV q 6 hrs pm nausea.	
	( )	Phenergan 12.5 –25 mg IV/ pr/ po q 6 hrs pm nausea.	Complications:
	( )	Ambien 10 mg po q hs pm sleep.	
	( )	Benadryl 25-50 mg IV/ po q6 hrs pm itching or sleep.	
	( )	Lovenox ____ mg sq ( ) bid ( ) daily begin:	Postoperative Diagnosis:
		Lovenox held because of:	
	( )	Nexium 40 mg IV/po daily.	
	( )	Dulcolax Supp pm except rectal cases.	
Other:	( )		
Labs	( )	( ) CBC ( ) Basic panel ( ) LFTs in a.m.	
	( )		
Xray	( )	Gastrografin swallow in a.m.	Signature:
Other:		Respiratory Protocol – No incentive Spirometry.	
			Patient Label:
Provider Signature:			

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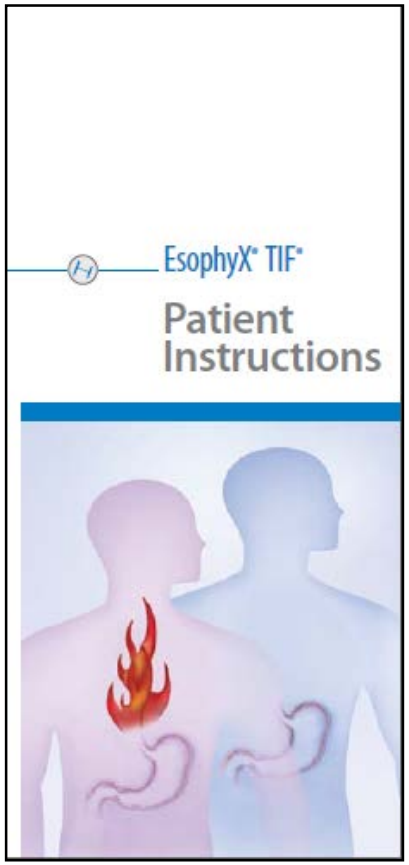
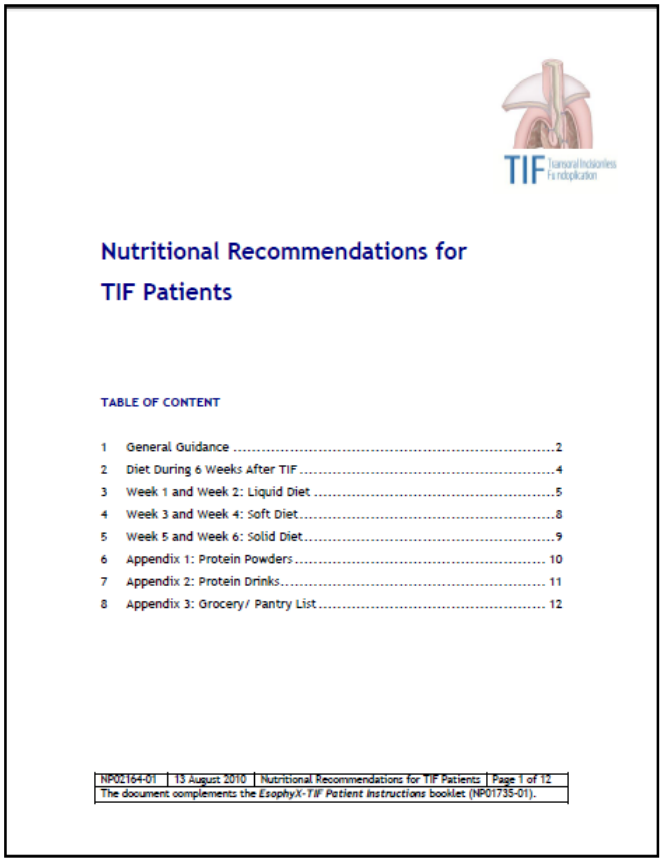
Educate

EsophyX TIF Patient Instructions



Recommendations for TIF Patients



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Considerations

- Unable to introduce EsophyX device?
- Stomach full of undigested food?
- Stomach cannot be distended?
- Brisk bleeding encountered at fastener deployment site?
- What if you see “free air”?
  - Gastrografin swallow?
  - CT scan?

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Questions?

THANK YOU!