

ENFit™ Transition Frequently Asked Questions for Hospitals & HCPs

Is the Boston Scientific portfolio ENFit compatible?

Yes, our Enteral Feeding portfolio is ENFit compatible.

My hospital has questions about ENFit - where can I get more information?

You can call, text, or email your Boston Scientific Representative anytime with ENFit questions. ENFit resources on BOX: https://boston scientific.app.box.com/folder/9087092269

Are there any other ENFit resources my hospital can reference?

- GEDSA: www.stayconnected.org
- GEDSA YouTube Channel: www.youtube.com/channel/UCa8w9VYxW8PZD Ewlol9bOO
- GEDSA Position Statement on ENFit FDA Letter: http://stayconnected.org/wp-content/uploads/2018/10/GEDSA-Position-Statement-on-FDA-Letter-2018-.pdf
- ➤ FDA Letter Encouraging Hospitals to move to ENFit:

https://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM619782.pdf

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/TubingandLuerMisconnections/default.htm

CMS Memo on ENFit:

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-14.pdf

ENFit™ Introduction

New standards have been implemented to address safety issues related to enteral feeding, resulting in the design of the ISO Standard 80369-3 Connection system. The ENFit Connector was designed to reduce the risk of a non-feeding tube device being connected to a feeding tube port. All enteral access devices, including feeding tubes, administration sets and enteral syringes will be impacted by these changes.

The New ENFit Connector

- Provides a way to reduce the risk of enteral tube feeding misconnections
- ➤ Addresses "bedside mis-connections" between feeding tubes, administration sets, medication, flush and bolus feeding syringes, and other enteral devices

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EndoVive[™]

Enteral Access Devices

One-Step Button™ Gastrostomy Device

Product Features

Cost Effective

➤ A cost-effective solution to provide low profile enteral feeding in one initial procedure

High-Grade Silicone Button-Bolstered Low Profile Initial Placement

- Designed for performance and consistent flow
- > Radiopaque silicone designed to enhance placement confirmation

Low Profile Design

- ➤ Low profile design helps reduce risk of accidental pull-out
- > Product flexibility at skin level designed to enhance patient comfort and cosmetic appeal

Universal 1.9 mm O.D. x 240 cm **Retrieval Snare**

> Designed to traverse scopes with a 2.0 mm or larger working channel

Anti-Reflux Valve

- Designed to help reduce gastric backflow
- Kit includes accessories designed to allow for gastric decompression

Multiple Sizes and Accessories

- Color-coded French sizes with corresponding feeding accessories and multiple lengths for broad patient coverage
- Specially designed round spacers to accommodate "in-between" sizes and short-term weight gain



One-Step Button Low Profile PEG Kits

Non-ENFit Codes	ENFit Codes	Description	Length (cm)	Color Code	Units
M005 6312 0	M005 0969 0	18Fr Low Profile PEG Kit, Pull	1.2	Yellow	Box 1
M005 6313 0	M005 0970 0	18Fr Low Profile PEG Kit, Pull	1.7	Yellow	Box 1
M005 6314 0	M005 0971 0	18Fr Low Profile PEG Kit, Pull	2.4	Yellow	Box 1
M005 6315 0	M005 0972 0	18Fr Low Profile PEG Kit, Pull	3.4	Yellow	Box 1
M005 6316 0	M005 0973 0	18Fr Low Profile PEG Kit, Pull	4.4	Yellow	Box 1
M005 6318 0	M005 0974 0	18Fr Low Profile PEG Kit, Push (Guidewire)	1.7	Yellow	Box 1
M005 6319 0	M005 0975 0	18Fr Low Profile PEG Kit, Push (Guidewire)	2.4	Yellow	Box 1
M005 6301 0	M005 0958 0	24Fr Low Profile PEG Kit, Pull	1.7	Blue	Box 1
M005 6302 0	M005 0959 0	24Fr Low Profile PEG Kit, Pull	2.4	Blue	Box 1
M005 6303 0	M005 0960 0	24Fr Low Profile PEG Kit, Pull	3.4	Blue	Box 1
M005 6304 0	M005 0961 0	24Fr Low Profile PEG Kit, Pull	4.4	Blue	Box 1
M005 6308 0	M005 0963 0	24Fr Low Profile PEG Kit, Push (Guidewire)	2.4	Blue	Box 1
M005 6309 0	M005 0962 0	24Fr Low Profile PEG Kit, Push (Guidewire)	3.4	Blue	Box 1
M005 6310 0	M005 0968 0	24Fr Low Profile PEG Kit, Push (Guidewire)	4.4	Blue	Box 1

Low Profile Button Replacement Feeding Tubes

Product Features

High-Grade Silicone Button-Bolstered Low Profile Replacement

- ➤ Radiopaque silicone designed to enhance placement confirmation
- Inserted through an existing stoma tract
- Low profile design helps reduce risk of accidental pull-out
- Product flexibility at skin level designed to enhance patient comfort and cosmetic appeal
- Designed to reduce gastric backflow
- ➤ Kit includes accessories designed to allow for gastric decompression
- Color-coded French sizes with corresponding feeding accessories and multiple lengths for broad patient coverage
- ➤ Specially designed round spacers to accommodate "in-between" sizes and short-term weight gain

KIT CONTENTS

- (1) Button Kit
- (2) Percutaneous Stoma Measuring Device (PSMD)
- (1) Spacer Disk Variety Pack
- (1) Right Angle
 Decompression Tube
- (1) Patient Care Kit
 - 60cc Catheter Tip Syringe
 - Right Angle Feeding Set
 - Bolus Feeding Set
 - EndoVive Patient Care Booklet



Low Profile Button Replacements

Non-ENFit Codes	ENFit Codes	Description	Length (cm)	Units
M005 6276 0	M005 0983 0	18Fr Low Profile Button Replacement	1.2	Box 1
M005 6277 0	M005 0984 0	18Fr Low Profile Button Replacement	1.7	Box 1
M005 6278 0	M005 0985 0	18Fr Low Profile Button Replacement	2.4	Box 1
M005 6279 0	M005 0986 0	18Fr Low Profile Button Replacement	3.4	Box 1
M005 6280 0	M005 0987 0	18Fr Low Profile Button Replacement	4.4	Box 1
M005 6282 0	M005 0941 0	24Fr Low Profile Button Replacement	1.7	Box 1
M005 6283 0	M005 0942 0	24Fr Low Profile Button Replacement	2.4	Box 1
M005 6284 0	M005 0943 0	24Fr Low Profile Button Replacement	3.4	Box 1
M005 6285 0	M005 0944 0	24Fr Low Profile Button Replacement	4.4	Box 1

Low Profile Button Accessories

Non-ENFit Codes	ENFit Codes	Description	Length (cm)	Units
M005 8040 1	M005 0112 1	18Fr Decompression Tube	1.2	Box 10
M005 8041 1	M005 0113 1	18Fr Decompression Tube	1.7	Box 10
M005 8042 1	M005 0114 1	18Fr Decompression Tube	2.4	Box 10
M005 8043 1	M005 0115 1	18Fr Decompression Tube	3.4	Box 10
M005 8044 1	M005 0116 1	18Fr Decompression Tube	4.4	Box 10
M005 8046 1	M005 0118 1	24Fr Decompression Tube	1.7	Box 10
M005 8047 1	M005 0119 1	24Fr Decompression Tube	2.4	Box 10
M005 8048 1	M005 0120 1	24Fr Decompression Tube	3.4	Box 10
M005 8049 1	M005 0121 1	24Fr Decompression Tube	4.4	Box 10
M005 8017 1	M005 0109 1	18Fr Bolus Straight Adapter		Box 10
M005 8018 1	M005 0106 1	18Fr Continuous Right-Angle Adapter		Box 10
M005 8023 1	M005 0110 1	24Fr Bolus Straight Adapter		Box 10
M005 8024 1	M005 0107 1	24Fr Continuous Right-Angle Adapter		Box 10



Standard Percutaneous Endoscopic Gastrostomy (PEG) Kit

Product Features

High-Grade Silicone Dome-Bolstered PEG Tube

- Designed for performance and consistent flow
- > Facilitates traction removal

Universal 1.9 mm O.D. x 240 cm Retrieval Snare

- Traverses scopes with a 2.0 mm or larger working channel
- Universal-sized snare, intended to eliminate the cost of a specialty snare

Double-Tier Tray Packaging

 Kit organization promotes procedural efficiency

External Bolsters

Two external bolster options: accommodates physician and patient needs: Round; T-Bar

Multiple Sizes and Accessories

- Multiple French sizes for broad patient coverage
- Separate feeding ports
- C-Clamp designed to help reduce risk of tube reflux and leaking

Standard PEG Kit

Non-ENFit Codes	ENFit Codes	Description	Units
M005 6820 1	M005 0904 1	20Fr Standard PEG Kit, Pull with Lidocaine Ampule	Box 2
M005 6821 1	M005 0905 1	20Fr Standard PEG Kit, Push with Lidocaine Ampule	Box 2
M005 6824 1	M005 0906 1	24Fr Standard PEG Kit, Pull with Lidocaine Ampule	Box 2
M005 6825 1	M005 0907 1	24Fr Standard PEG Kit, Push with Lidocaine Ampule	Box 2

PEG Accessories

Non-ENFit Codes	ENFit Codes	Description	Units
M005 8064 1	M005 0126 1	20Fr Y-Ports	Box 10
M005 8065 1	M005 0127 1	24Fr Y-Ports	Box 10
M005 8073 1	N/A	20Fr Round Bolsters	Box 10
M005 8078 1	N/A	C-Clamps (Fits 20Fr and 24Fr)	Box 10

EndoVive™

Enteral Access Devices

Safety Percutaneous Endoscopic Gastrostomy (PEG) Kit

Product Features

Deluxe Safety PEG Procedure Kit

- High-grade silicone dome-bolstered PEG tube
- ➤ ChloraPrep® Skin Preparation
- Universal 1.9 mm O.D. x 240 cm retrieval snare
- ➤ Double-tier tray packaging
- ➤ Two external bolsters
- ➤ Multiple sizes and accessories
- ➤ Available for push and pull methods

Safety Trocar Catheter

- Needle tip protector designed to engage when the needle stylet is removed from the needle cannula
- Designed to allow re-activation by replacing the needle stylet back into the needle cannula

Safety-Shielded Scalpel

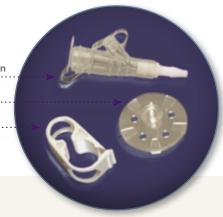
➤ Thumb-activated safety mechanism retracts spring-loaded No. 11 surgical blade into handle

SafetyGlide® Shielded Injection Needle

- ➤ 22 gauge x 1.5" needle designed for injection into abdominal wall
- Shielding mechanism designed for one-finger activation

PEG Accessories

- ➤ Y-Ports
- ➤ Round Bolsters
- ➤ T-Bar Bolster
- ➤ C-Clamps



Y-Port with Stepped Design

Round Bolster

C-Clamp

Standard PEG Kit

Non-ENFit Codes	ENFit Codes	Description	Units
M005 6820 1	M005 0904 1	20Fr Standard PEG Kit, Pull with Lidocaine Ampule	Box 2
M005 6821 1	M005 0905 1	20Fr Standard PEG Kit, Push with Lidocaine Ampule	Box 2
M005 6824 1	M005 0906 1	24Fr Standard PEG Kit, Pull with Lidocaine Ampule	Box 2
M005 6825 1	M005 0907 1	24Fr Standard PEG Kit Push with Lidocaine Ampule	Box 2

PEG Accessories

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M005 8073 1	N/A	20Fr Round Bolsters	Box 10
M005 8078 1	N/A	C-Clamps (Fits 20Fr and 24Fr)	Box 10

EndoVive

Enteral Access Devices

Through-The-PEG (TTP) Jejunal Feeding Tube

Product Features

Innovative Device Design

- > Designed for placement through an existing Standard PEG
 - ➤ 68 cm length, 8.5Fr TTP J-Tube compatible with 20Fr PEG
 - ➤ 68 cm length, 12Fr TTP J-Tube compatible with 24Fr PEG
- ➤ Available in Pigtail Tip and Bent Tip designs, each with a suture loop intended to facilitate distal tip anchoring past the Ligament of Treitz
- ➤ Compatible with both Pull and Push (over-the-wire) Placement Techniques



> Radiopaque material facilitates fluoroscopic visualization

Temp Tip

- > Temporary tapered tip designed to provide smooth tracking into the jejunum to help ensure proper placement
- ➤ Temp Tip is designed to dissolve at body temperature permitting utilization of the full distal tip lumen diameter which may help reduce premature tube clogging

Hollow Stiffening Stylet

> Provides added stiffness designed to improve pushability and permit greater physician control during placement

Recommended Anchoring Device

- ➤ Resolution Clip or Resolution 360 Clip
- > Physician controlled rotation designed to allow easier grasping of J-Tube suture loop.

EndoVive TTP Jejunal Feeding Tube @

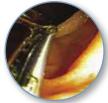
Order Number	Description	Tip Style	Units
M005 6632 0	8.5Fr TTP Jejunal Feeding Tube	Bent Tip	Box 1
M005 6633 0	8.5Fr TTP Jejunal Feeding Tube	Pigtail Tip	Box 1
M005 6634 0	12Fr TTP Jejunal Feeding Tube	Bent Tip	Box 1
M005 6635 0	12Fr TTP Jejunal Feeding Tube	Pigtail Tip	Box 1

Recommended Anchoring Device

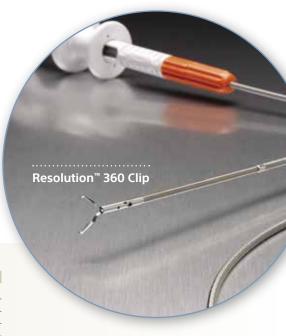
Description	Working Length (cm)	Minimum Working Channel (mm)	Clip Opening (mm)	Units
Resolution® 360 Clip	155	2.8	11	Each
Resolution 360 Clip	155	2.8	11	Box 10
Resolution 360 Clip	155	2.8	11	Box 20
Resolution 360 Clip	235	2.8	11	Each
Resolution 360 Clip	235	2.8	11	Box 10
Resolution 360 Clip	235	2.8	11	Box 20
Resolution 360 Clip	235	2.8	11	Box 40
	Resolution* 360 Clip Resolution 360 Clip Resolution 360 Clip Resolution 360 Clip Resolution 360 Clip Resolution 360 Clip	Description (cm) Resolution* 360 Clip 155 Resolution 360 Clip 155 Resolution 360 Clip 155 Resolution 360 Clip 235 Resolution 360 Clip 235 Resolution 360 Clip 235	Description (cm) Channel (mm) Resolution* 360 Clip 155 2.8 Resolution 360 Clip 155 2.8 Resolution 360 Clip 155 2.8 Resolution 360 Clip 235 2.8	Description (cm) Channel (mm) (mm) Resolution* 360 Clip 155 2.8 11 Resolution 360 Clip 155 2.8 11 Resolution 360 Clip 155 2.8 11 Resolution 360 Clip 235 2.8 11 Resolution 360 Clip 235 2.8 11 Resolution 360 Clip 235 2.8 11



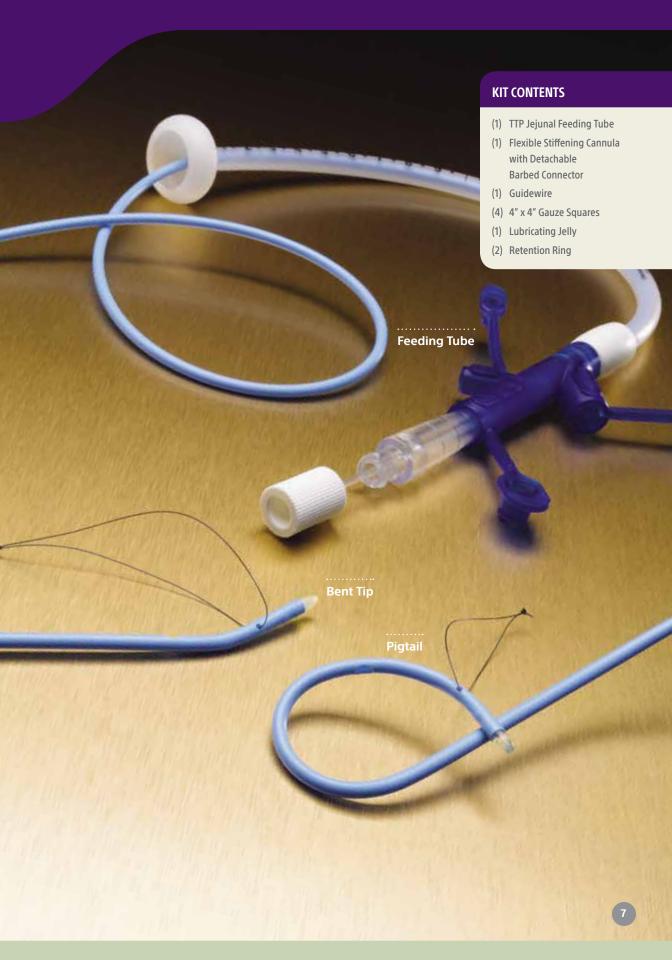
Resolution 360 Clip grasping suture loop

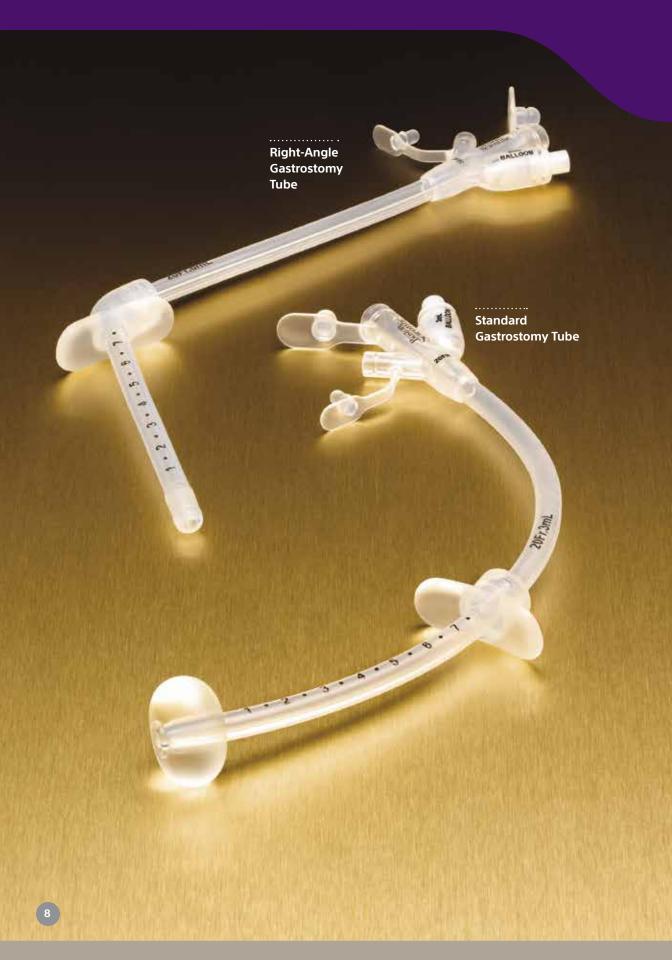


Resolution 360 Clip anchoring suture and jejunal tube to jejunal wall



^{*}Distal ENFit adapter can be used in conjunction with the J-tube feeding port to accommodate ENFit syringes.





EndoVive™

Enteral Access Devices

Standard Balloon Replacement Kits

Product Features

Low Profile "Pancake" Shaped Balloon

- > Designed to offer the deflation characteristics of a balloon for insertion and removal that may be more comfortable for the patient
- ➤ Consistent 6 ml balloon inflation across all sizes (12Fr = 4ml)

Replacement Gastrostomy Tube with Optional Right-Angled External Bolster

- ➤ Designed to minimize the potential tube kinking when it's taped down
- Designed to minimize premature pull out due to shape of the tube
- > Separate medication and feeding ports
- ➤ Clear shaft for internal lumen visualization

KIT CONTENTS

- (1) Balloon Replacement with Straight or Right-Angle **External Bolster**
- (2) 4"x 4" Gauze Pads
- (1) 6 ml Syringe
- (1) Lubricating Jelly

Replacement G-Tubes

Order Number	Description	Units
M005 8204 0	12Fr Replacement G-Tube, Straight	Box 1
M005 8205 0	14Fr Replacement G-Tube, Straight	Box 1
M005 8206 0	16Fr Replacement G-Tube, Straight	Box 1
M005 8207 0	18Fr Replacement G-Tube, Straight	Box 1
M005 8208 0	20Fr Replacement G-Tube, Straight	Box 1
M005 8286 0	22Fr Replacement G-Tube, Straight	Box 1
M005 8209 0	24Fr Replacement G-Tube, Straight	Box 1
M005 8210 0	28Fr Replacement G-Tube, Straight	Box 1
M005 8211 0	12Fr Replacement G-Tube, Right-Angle	Box 1
M005 8212 0	14Fr Replacement G-Tube, Right-Angle	Box 1
M005 8213 0	16Fr Replacement G-Tube, Right-Angle	Box 1
M005 8214 0	18Fr Replacement G-Tube, Right-Angle	Box 1
M005 8215 0	20Fr Replacement G-Tube, Right-Angle	Box 1
M005 8287 0	22Fr Replacement G-Tube, Right-Angle	Box 1
M005 8216 0	24Fr Replacement G-Tube, Right-Angle	Box 1
M005 8217 0	28Fr Replacement G-Tube, Right-Angle	Box 1

EndoVive

Enteral Access Devices

EndoVive Gastrostomy Tube with ENFit Connector

Right Angle Bolster Standard and ENFit G-tubes

Designed to:

- ➤ Be less obtrusive
- Reduce or limit premature pull out and potential tube kinking if the tube is taped down and may be more comfortable with the patient
- ➤ Make sure all appropriate service lines in your healthcare system are ready to use ENFit enteral connectors. Please contact your Boston Scientific Sales Representative for support with ENFit enteral connectors.



Replacement G-Tubes with ENFit

NEW Order Number	Description	Length (cm)
M00509881	Gastrostomy Tube, Straight, Replacement with ENFit	12Fr
M00509891	Gastrostomy Tube, Straight, Replacement with ENFit	14Fr
M00509901	Gastrostomy Tube, Straight, Replacement with ENFit	16Fr
M00509911	Gastrostomy Tube, Straight, Replacement with ENFit	18Fr
M00509921	Gastrostomy Tube, Straight, Replacement with ENFit	20Fr
M00509941	Gastrostomy Tube, Straight, Replacement with ENFit	24Fr
M00509961	Gastrostomy Tube, right angle, Replacement with ENFit	12Fr
M00509971	Gastrostomy Tube, right angle, Replacement with ENFit	14Fr
M00509981	Gastrostomy Tube, right angle, Replacement with ENFit	16Fr
M00509991	Gastrostomy Tube, right angle, Replacement with ENFit	18Fr
M00510001	Gastrostomy Tube, right angle, Replacement with ENFit	20Fr
M00510011	Gastrostomy Tube, right angle, Replacement with ENFit	22Fr
M00510021	Gastrostomy Tube, right angle, Replacement with ENFit	24Fr

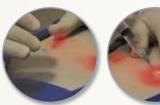


One-Step Button[™] Gastrostomy Device

Procedure Guide

STEP 1 Button Site Selection

- Introduce gastroscope; insufflate stomach.
- Transilluminate abdominal wall with the light of the gastroscope.
- ➤ Apply finger pressure at the point where transillumination is most clear.
- Use anesthetic at the proposed stoma site.
- With scalpel, make a 1.5 cm incision at the selected site.







STEP 2 Percutaneous Stoma Measuring Device (PSMD) Placement

Insert the PSMD through the skin incision and into the stomach under direct vision of the endoscopist.

- Grasp the PSMD cannula with the snare.
- Close the snare around the cannula.
- Extend the thumb to raise the ring. This action will cause the tri-leaflet (located distally) to gather and "BLOOM" open.





STEP 3 Selection of the Appropriate One-Step Button

Remove the needle from the cannula. Pull back gently on the measuring device with the leaflets in the "BLOOM" or open position. The measurement is then obtained by noting the centimeter (cm) length indicated by the black markings found on the PSMD cannula

Read the exposed black markings on the PSMD to determine the size of the One-Step Button to be used.

STEP 4 Placement of Insertion Wire

- Pass the insertion wire down the already placed PSMD cannula. Upon visualization of the insertion wire, grasp the wire with the snare.
- Withdraw the endoscope, snare, and the attached snared wire.
- Unlock the PSMD and completely compress the Thumb Ring until it lies flat against the top of the spool's barrel.





STEP 5 Attachment of the One-Step Catheter to the Insertion Wire

Pass the insertion wire through the One-Step wire loop.





STEP 6 Advancing Catheter

When the red strip is visible, advance the catheter very slowly. With your hand, provide coutertraction on the abdomen around the stoma site. Advance the catheter in small increments until the folded encased wings of the One-Step Button have exited the abdominal wall.

- Remove Sheath.
- Grasp the black suture and pull up along red strip.





Through-The PEG (TTP) Jejunal Feeding Tube

Procedure Guide for Pull Method

STEP 1

Maintaining insufflation and visualization of the gastrostomy tube internal bolster, advance the TTP J-Tube through the existing gastrostomy tube until the suture loop and tip have entered the stomach.







STEP 2

Pass a sterile biopsy forceps or hemostasis clipping device, such as the Resolution™ 360 Clip, through the endoscope and grasp the suture loop at the tip of the TTP J-Tube.





STEP 3

Using the biopsy forceps or hemostasis clip, advance the TTP J-Tube as far as visual control can be maintained.

STEP 4

Clip the suture to the wall of the jejunum. Gently withdraw the endoscope leaving the TTP J-Tube in place.

STEP 5

Visually confirm that the position of the tip of the TTP J-Tube is maintained as the endoscope or clipping device, is withdrawn. Confirm the TTP J-Tube is not looped in the stomach.

STEP 6

Once the endoscope is removed, seat the TTP J-Tube's hub adapter securely in the existing gastrostomy tube. Secure the distal portion of the TTP J-Tube hub to the existing gastrostomy tube by snapping the two retention ring halves together over the hub and gastrostomy tube.

Enteral Feeding

Coding

CPT* Code ¹	Description
Gastrostomy Tube Initial Placement	
43246	Esophagogastroduodenoscopy, flexible, transoral; with directed placement of percutaneous gastrostomy tube
49440	Insertion of gastrostomy tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report
Gastrostomy Tube Replacement/Reposition	
43762*	Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance, not requiring revision of gastrostomy tract
43763*	Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance, requiring revision of gastrostomy tract
43761	Repositioning of a naso- or oro-gastric feeding tube, through the duodenum for enteric nutrition
49450	Replacement of gastrostomy or cecostomy (or other colonic) tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report
Jejunostomy Tube	
44373	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with conversion of percutaneous gastrostomy tube to percutaneous jejunostomy tube
49440	Insertion of gastrostomy tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report
49446	Conversion of gastrostomy tube to gastro-jejunostomy tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report
49452	Replacement of gastro-jejunostomy tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report
Other Procedures	
	Machanical removal of obstructive material from gastrostomy, duodenostomy, jaiunostomy, gastro-jaiunostomy, or

49460

Mechanical removal of obstructive material from gastrostomy, duodenostomy, jejunostomy, gastro-jejunostomy, or cecostomy (or other colonic) tube, any method, under fluoroscopic guidance including contrast injection(s), if performed, image documentation and report

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^{*}Effective January 1, 2019 CPT Code 43760 deleted and replaced with codes 43762 and 43763.