

EndoVive®
Enteral Access Devices



Product and Procedure Guide

**Boston
Scientific**



vive =

Endo = Endoscopic. Vive = Live.

EndoVive represents endoscopic accessibility to feed and provide nutrition to patients who do not have the ability to feed by mouth.



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EndoVive® Initial Placements

- One-Step Button™ Gastrostomy Device
- Standard Percutaneous Endoscopic Gastrostomy (PEG) Kit
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- One-Step Button
- Jejunal Feeding Tube Procedure

EndoVive

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

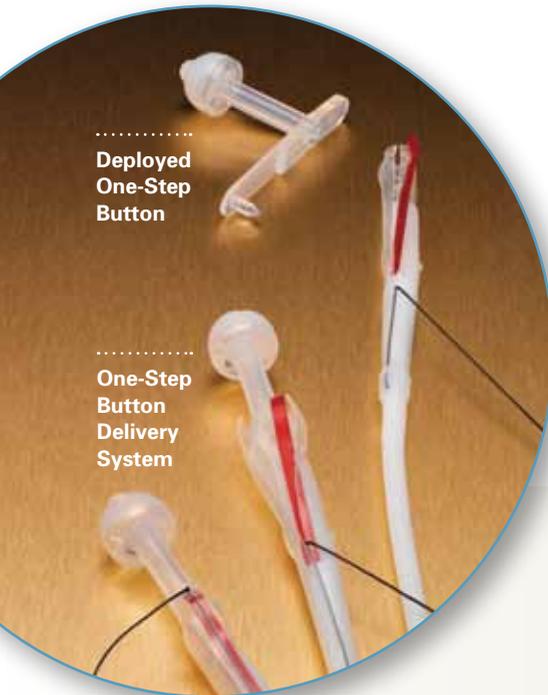
- Designed to traverse scopes with a 2.0 mm or larger working channel

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

| Order Number | Description | Length (cm) | Color Code | Units |
|--------------|--|-------------|------------|-------|
| M00563120 | 18Fr Low Profile PEG Kit, Pull | 1.2 | Yellow | Box 1 |
| M00563130 | 18Fr Low Profile PEG Kit, Pull | 1.7 | Yellow | Box 1 |
| M00563140 | 18Fr Low Profile PEG Kit, Pull | 2.4 | Yellow | Box 1 |
| M00563150 | 18Fr Low Profile PEG Kit, Pull | 3.4 | Yellow | Box 1 |
| M00563160 | 18Fr Low Profile PEG Kit, Pull | 4.4 | Yellow | Box 1 |
| M00563180 | 18Fr Low Profile PEG Kit, Push (Guidewire) | 1.7 | Yellow | Box 1 |
| M00563190 | 18Fr Low Profile PEG Kit, Push (Guidewire) | 2.4 | Yellow | Box 1 |
| M00563010 | 24Fr Low Profile PEG Kit, Pull | 1.7 | Blue | Box 1 |
| M00563020 | 24Fr Low Profile PEG Kit, Pull | 2.4 | Blue | Box 1 |
| M00563030 | 24Fr Low Profile PEG Kit, Pull | 3.4 | Blue | Box 1 |
| M00563040 | 24Fr Low Profile PEG Kit, Pull | 4.4 | Blue | Box 1 |
| M00563080 | 24Fr Low Profile PEG Kit, Push (Guidewire) | 2.4 | Blue | Box 1 |
| M00563090 | 24Fr Low Profile PEG Kit, Push (Guidewire) | 3.4 | Blue | Box 1 |
| M00563100 | 24Fr Low Profile PEG Kit, Push (Guidewire) | 4.4 | Blue | Box 1 |

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**Percutaneous Stoma
 Measuring Device (PSMD)**

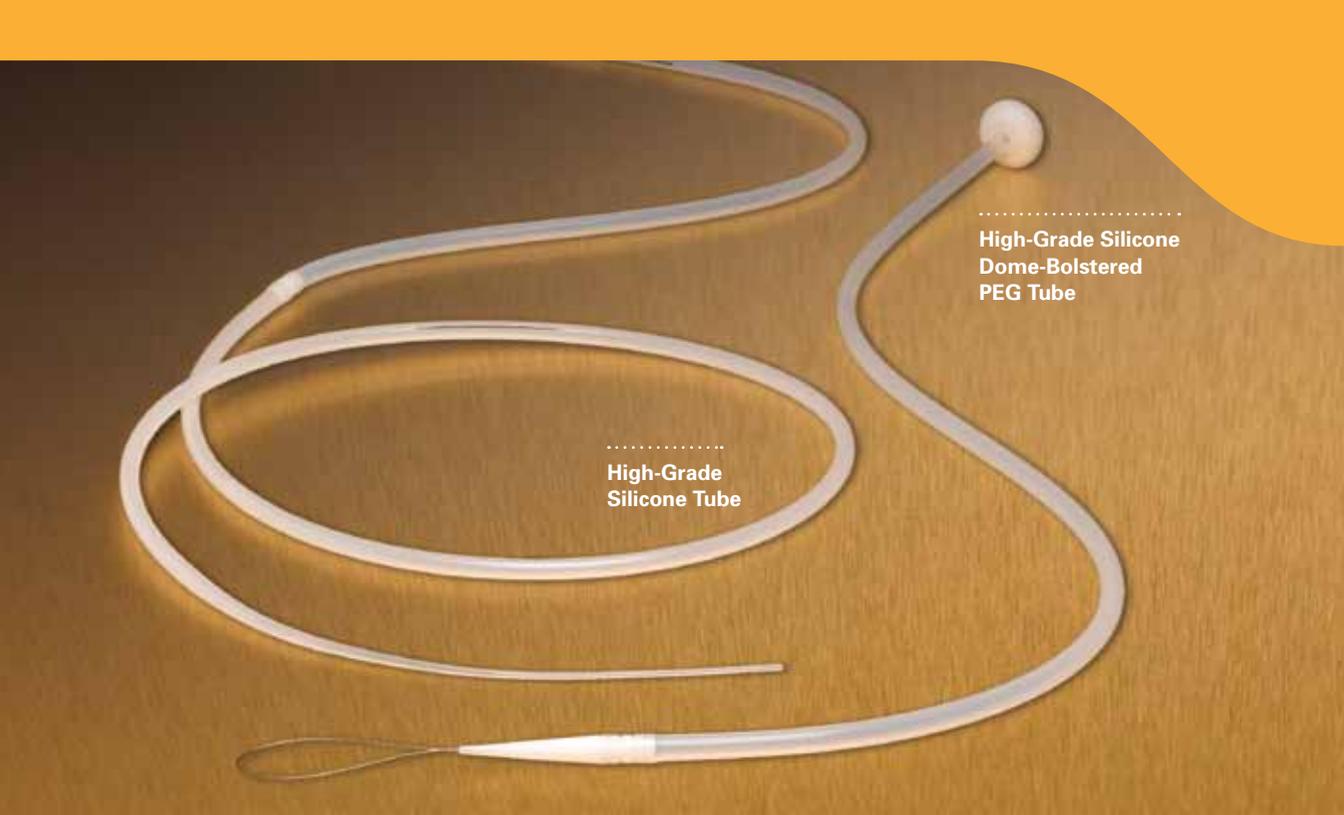
.....
One-Step Button Delivery System

One-Step Button™ and Low Profile Button Accessories

| Order Number | Description | Length (cm) | Color Code | Units |
|--------------|-------------------------------------|-------------|------------|--------|
| M00580401 | 18Fr Decompression Tube | 1.2 | Yellow | Box 10 |
| M00580411 | 18Fr Decompression Tube | 1.7 | Yellow | Box 10 |
| M00580421 | 18Fr Decompression Tube | 2.4 | Yellow | Box 10 |
| M00580431 | 18Fr Decompression Tube | 3.4 | Yellow | Box 10 |
| M00580441 | 18Fr Decompression Tube | 4.4 | Yellow | Box 10 |
| M00580461 | 24Fr Decompression Tube | 1.7 | Blue | Box 10 |
| M00580471 | 24Fr Decompression Tube | 2.4 | Blue | Box 10 |
| M00580481 | 24Fr Decompression Tube | 3.4 | Blue | Box 10 |
| M00580491 | 24Fr Decompression Tube | 4.4 | Blue | Box 10 |
| M00580171 | 18Fr Bolus Straight Adapter | | Yellow | Box 10 |
| M00580181 | 18Fr Continuous Right-Angle Adapter | | Yellow | Box 10 |
| M00580231 | 24Fr Bolus Straight Adapter | | Blue | Box 10 |
| M00580241 | 24Fr Continuous Right-Angle Adapter | | Blue | Box 10 |

KIT CONTENTS

- (1) One-Step Button Kit
- (1) Percutaneous Stoma Measuring Device (PSMD)
- (1) Spacer Disc Variety Pack
- (1) Right Angle Decompression Tube
- (1) Patient Care Kit



High-Grade Silicone Dome-Bolstered PEG Tube

High-Grade Silicone Tube

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

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

| Order Number | Description | Units |
|--------------|-----------------------------|-------|
| M00568201 | 20Fr Standard PEG Kit, Pull | Box 2 |
| M00568211 | 20Fr Standard PEG Kit, Push | Box 2 |
| M00568241 | 24Fr Standard PEG Kit, Pull | Box 2 |
| M00568251 | 24Fr Standard PEG Kit, Push | Box 2 |

PEG Accessories

| Order Number | Description | Units |
|--------------|-------------------------------|--------|
| M00580641 | 20Fr Y-Ports | Box 10 |
| M00580651 | 24Fr Y-Ports | Box 10 |
| M00580731 | 20Fr Round Bolsters | Box 10 |
| M00580781 | C-Clamps (Fits 20Fr and 24Fr) | Box 10 |

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 1/2" needle designed for injection into abdominal wall
- Shielding mechanism designed for one-finger activation

PEG Accessories

- Y-Ports
- Round Bolsters
- C-Clamps

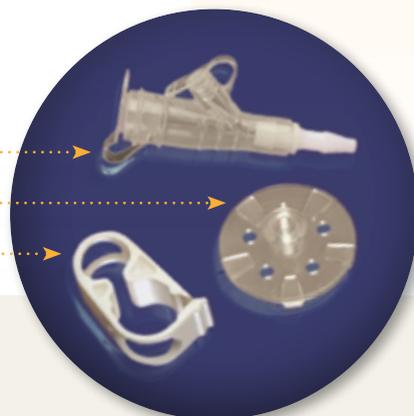
Plastic Xylocaine Ampule with Luer-Lok® Neck

- Plastic vial designed to reduce potential for glass shard injuries
- Twist-off top yields a Luer-Lok neck
- Luer-Lok neck designed for ready attachment to the luer-tipped safety syringe

Y-Port with Stepped Design

Round Bolster

C-Clamp



Safety PEG Kit with Xylocaine® Ampule

| Order Number | Description | Units |
|--------------|--|-------|
| M00566461 | 20Fr Safety PEG Kit Pull with Xylocaine Ampule | Box 2 |
| M00566471 | 20Fr Safety PEG Kit Push with Xylocaine Ampule | Box 2 |
| M00566481 | 24Fr Safety PEG Kit Pull with Xylocaine Ampule | Box 2 |
| M00566491 | 24Fr Safety PEG Kit Push with Xylocaine Ampule | Box 2 |

PEG Accessories

| Order Number | Description | Units |
|--------------|-------------------------------|--------|
| M00580641 | 20Fr Y-Ports | Box 10 |
| M00580651 | 24Fr Y-Ports | Box 10 |
| M00580731 | 20Fr Round Bolsters | Box 10 |
| M00580781 | C-Clamps (Fits 20Fr and 24Fr) | Box 10 |

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

Flexima Material

- 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



Resolution Clip grasping



Resolution Clip anchoring suture and jejunal tube to gastric wall



Resolution Clip

EndoVive TTP Jejunal Feeding Tube

| Order Number | Description | Tip Style | Units |
|--------------|--------------------------------|-------------|-------|
| M00566320 | 8.5Fr TTP Jejunal Feeding Tube | Bent Tip | Box 1 |
| M00566330 | 8.5Fr TTP Jejunal Feeding Tube | Pigtail Tip | Box 1 |
| M00566340 | 12Fr TTP Jejunal Feeding Tube | Bent Tip | Box 1 |
| M00566350 | 12Fr TTP Jejunal Feeding Tube | Pigtail Tip | Box 1 |

Recommended Anchoring Device

| Order Number | Description | Working Length (cm) | Minimum Working Channel (mm) | Clip Opening (mm) | Units |
|--------------|------------------|---------------------|------------------------------|-------------------|--------|
| M00522610 | Resolution® Clip | 235 | 2.8 | 11 | Each |
| M00522611 | Resolution Clip | 235 | 2.8 | 11 | Box 10 |
| M00522612 | Resolution Clip | 235 | 2.8 | 11 | Box 20 |

KIT CONTENTS

- (1) TTP Jejunal Feeding Tube
- (1) Flexible Stiffening Cannula with Detachable Barbed Connector
- (1) Guidewire
- (4) 4" x 4" Gauze Squares
- (1) Lubricating Jelly
- (2) Retention Ring



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Feeding Tube

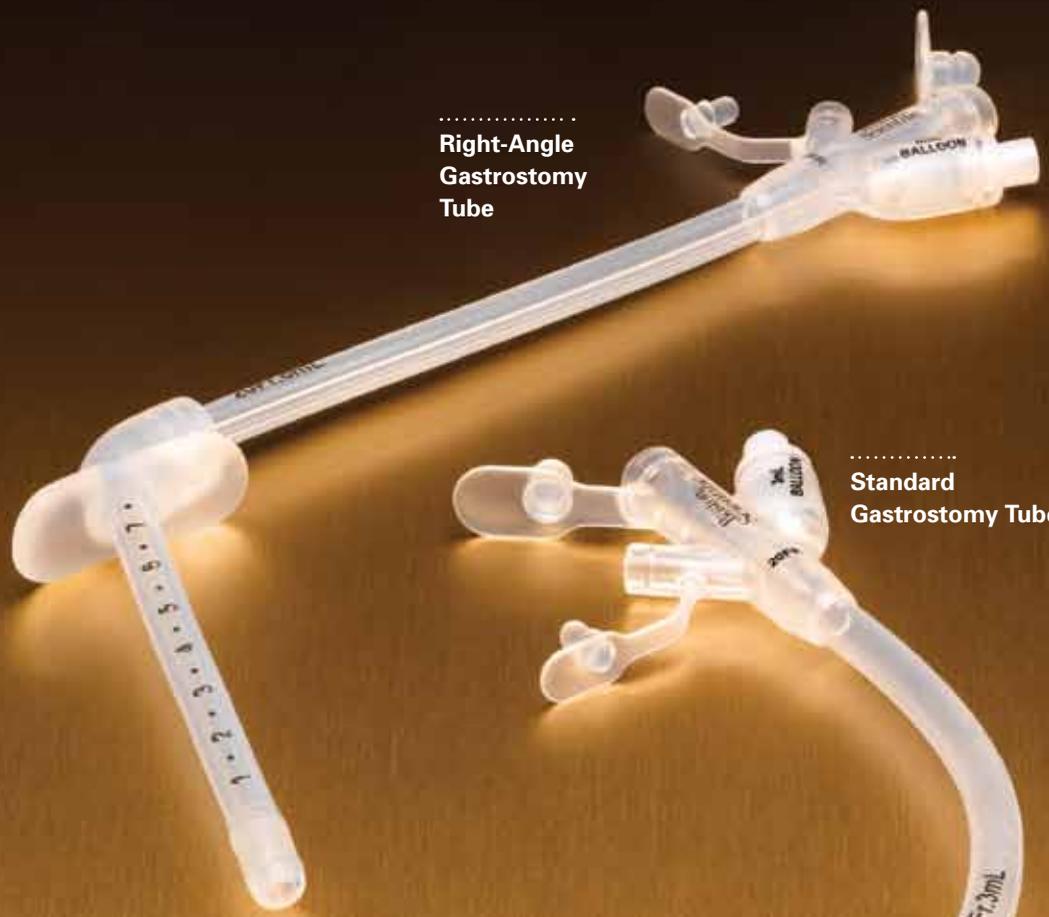


.....
Bent Tip



.....
Pigtail

.....
**Right-Angle
Gastrostomy
Tube**



.....
**Standard
Gastrostomy Tube**



Gastrostomy Tubes

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

Standard Profile Gastrostomy 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
- Engineered to minimize the likelihood that the Y-Port and the feeding tube adapter will come apart and spill the contents of the nutrition bag
- Separate medication and feeding ports
- Clear shaft for internal lumen visualization

KIT CONTENTS

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

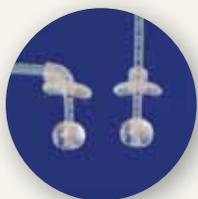
Standard Profile Balloon Replacement Feeding Tubes

| Order Number | Description | Units |
|--------------|--------------------------------------|-------|
| M00582040 | 12Fr Replacement G-Tube, Straight | Box 1 |
| M00582050 | 14Fr Replacement G-Tube, Straight | Box 1 |
| M00582060 | 16Fr Replacement G-Tube, Straight | Box 1 |
| M00582070 | 18Fr Replacement G-Tube, Straight | Box 1 |
| M00582080 | 20Fr Replacement G-Tube, Straight | Box 1 |
| M00582860 | 22Fr Replacement G-Tube, Straight | Box 1 |
| M00582090 | 24Fr Replacement G-Tube, Straight | Box 1 |
| M00582100 | 28Fr Replacement G-Tube, Straight | Box 1 |
| M00582110 | 12Fr Replacement G-Tube, Right-Angle | Box 1 |
| M00582120 | 14Fr Replacement G-Tube, Right-Angle | Box 1 |
| M00582130 | 16Fr Replacement G-Tube, Right-Angle | Box 1 |
| M00582140 | 18Fr Replacement G-Tube, Right-Angle | Box 1 |
| M00582150 | 20Fr Replacement G-Tube, Right-Angle | Box 1 |
| M00582870 | 22Fr Replacement G-Tube, Right-Angle | Box 1 |
| M00582160 | 24Fr Replacement G-Tube, Right-Angle | Box 1 |
| M00582170 | 28Fr Replacement G-Tube, Right-Angle | Box 1 |

Enteral Access Balloon Side-by-Side Comparison

New Balloon Design Features and Benefits

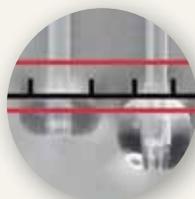
Right Angle Bolster Option on Standard G-tubes



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

Pancake Shaped Balloon



Designed to:

- Be durable and comfortable
- Increase surface area contact with gastric wall which may result in less leakage through the stoma
- Be lighter weight than other devices

Balloon Durability**

New BSC balloon lasted **3.8 times** longer than Kimberly-Clark® Mic® Device in simulated gastric acid.

Balloon Wall Thickness**

Average thickness of new BSC standard G-tube balloon is **two times** that of Kimberly-Clark Mic Device. Designed to be more durable and last longer.

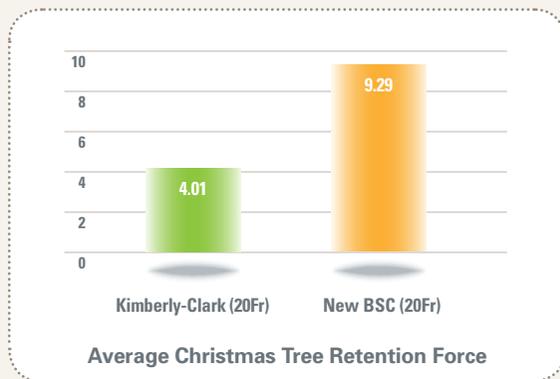
Retention Force**

The force required to pull a standard Christmas tree adapter from the new Boston Scientific standard replacement devices is **two times** greater than Kimberly-Clark Mic Device.

| AVERAGE BALLOON THICKNESS* | |
|----------------------------|---------------------------------|
| Device | Average Balloon Thickness (in.) |
| Kimberly-Clark | 0.020 |
| BSC New | 0.040 |

*All balloons measured were greater than 16 French

| AVERAGE CHRISTMAS TREE RETENTION FORCE | |
|--|---|
| Device | Average X-mas Tree Retention Force (lb) |
| Kimberly-Clark | 4.01 |
| BSC New | 9.29 |



**Data on file at Boston Scientific Corporation



Performance and Consistency

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

Low Profile Button Replacements

| Order Number | Description | Length (cm) | Color Code | Units |
|--------------|-------------------------------------|-------------|------------|-------|
| M00562760 | 18Fr Low Profile Button Replacement | 1.2 | Yellow | Box 1 |
| M00562770 | 18Fr Low Profile Button Replacement | 1.7 | Yellow | Box 1 |
| M00562780 | 18Fr Low Profile Button Replacement | 2.4 | Yellow | Box 1 |
| M00562790 | 18Fr Low Profile Button Replacement | 3.4 | Yellow | Box 1 |
| M00562800 | 18Fr Low Profile Button Replacement | 4.4 | Yellow | Box 1 |
| M00562820 | 24Fr Low Profile Button Replacement | 1.7 | Blue | Box 1 |
| M00562830 | 24Fr Low Profile Button Replacement | 2.4 | Blue | Box 1 |
| M00562840 | 24Fr Low Profile Button Replacement | 3.4 | Blue | Box 1 |
| M00562850 | 24Fr Low Profile Button Replacement | 4.4 | Blue | Box 1 |

Low Profile Button Accessories

| Order Number | Description | Length (cm) | Color Code | Units |
|--------------|-------------------------------------|-------------|------------|--------|
| M00580401 | 18Fr Decompression Tube | 1.2 | Yellow | Box 10 |
| M00580411 | 18Fr Decompression Tube | 1.7 | Yellow | Box 10 |
| M00580421 | 18Fr Decompression Tube | 2.4 | Yellow | Box 10 |
| M00580431 | 18Fr Decompression Tube | 3.4 | Yellow | Box 10 |
| M00580441 | 18Fr Decompression Tube | 4.4 | Yellow | Box 10 |
| M00580461 | 24Fr Decompression Tube | 1.7 | Blue | Box 10 |
| M00580471 | 24Fr Decompression Tube | 2.4 | Blue | Box 10 |
| M00580481 | 24Fr Decompression Tube | 3.4 | Blue | Box 10 |
| M00580491 | 24Fr Decompression Tube | 4.4 | Blue | Box 10 |
| M00580171 | 18Fr Bolus Straight Adapter | | Yellow | Box 10 |
| M00580181 | 18Fr Continuous Right-Angle Adapter | | Yellow | Box 10 |
| M00580231 | 24Fr Bolus Straight Adapter | | Blue | Box 10 |
| M00580241 | 24Fr Continuous Right-Angle Adapter | | Blue | Box 10 |

| Medicare Physician, Hospital Outpatient, and ASC Payments | | Physician ² | | Facility ³ | |
|---|---|------------------------|------------------------|-----------------------------|----------------------|
| | | MD Payment In-Office | MD Payment In-Facility | Hospital Outpatient Payment | ASC Facility Payment |
| CPT® Code ¹ | Description | | | | |
| Gastrostomy Tube Initial Placement | | | | | |
| 43246 | Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with directed placement of percutaneous gastrostomy tube | \$257 | \$257 | \$612 | \$344 |
| 49440 | Insertion of gastrostomy tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report | \$1,090 | \$232 | \$612 | \$344 |
| Gastrostomy Tube Replacement/Reposition | | | | | |
| 43760 | Change of gastrostomy tube, percutaneous, without imaging or endoscopic guidance | \$404 | \$50 | \$162 | \$91 |
| 49450 | Replacement of gastrostomy or cecostomy (or other colonic) tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report | \$719 | \$69 | \$436 | \$245 |
| 43761 | Repositioning of the gastric feeding tube, through the duodenum for enteric nutrition | \$121 | \$106 | \$612 | \$344 |
| Jejunostomy Tube | | | | | |
| 49452 | Replacement of gastro-jejunostomy tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report | \$905 | \$147 | \$436 | \$245 |
| 49446 | Conversion of gastrostomy tube to gastro-jejunostomy tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report | \$1,008 | \$170 | \$612 | \$344 |
| 44373 | Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with conversion of percutaneous gastrostomy tube to percutaneous jejunostomy tube | \$210 | \$210 | \$702 | \$395 |
| 49440 | Insertion of gastrostomy tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report | \$1,090 | \$232 | \$612 | \$344 |
| Other Procedures | | | | | |
| 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 | \$793 | \$50 | \$436 | \$245 |

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Medicare Hospital Inpatient Payment

Inpatient payment information not shown because the enteral feeding procedure will rarely, if ever, be the primary reason for a hospital admission.

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all inclusive list. We recommend consulting your relevant manuals for appropriate coding options.



Use your smartphone to scan and link to GuidePoint to view updated pricing information about reimbursement or visit www.bostonscientific.com/reimbursement

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Boston Scientific does not promote the use of its products outside their FDA-approved label.

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.
- Inject 5cc of 1% Xylocaine® into 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 countertraction 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.

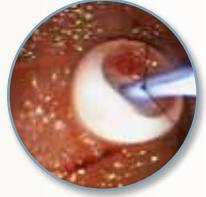


Through-The PEG (TTP) Jejunal Feeding Tube

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 Resolution® Clip through the endoscope and grasp the suture loop at the tip of the TTP J-Tube.



STEP 3

- Using the Resolution 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.



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Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.

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