

Get closure.

One-to-one rotation for precise placement and a tissue-grasping design for secure closure



Instinct Plus[®]
ENDOSCOPIC CLIPPING DEVICE

Reengineered for smoother operation and responsive handling, the Instinct Plus Endoscopic Clipping Device combines strength with the simplicity of one-step deployment.

Strength and security

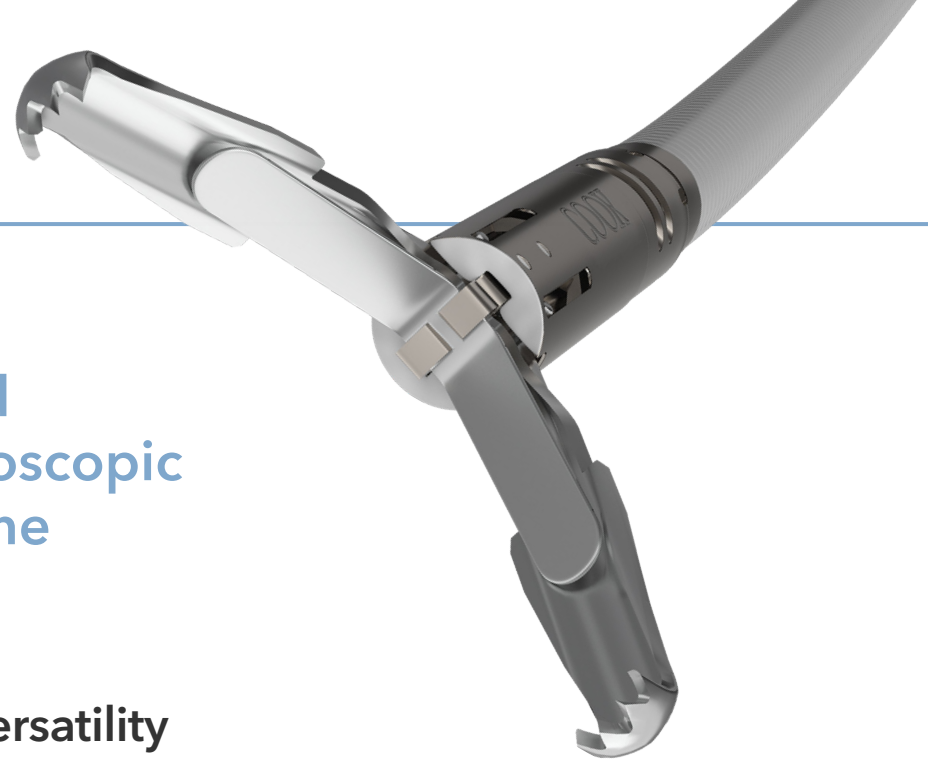
- Strong clip retention¹
- Multiple anchoring tips on the clip to aid in dragging and holding tissue
- Clips reinforced with nitinol, a superelastic shape-memory alloy

Responsive handling

- Adjustable clip span that opens up to 16 mm wide
- One-to-one rotation from the handle to the tip
- Ability to open and close up to five times for repositioning

Versatility

- Compatibility with both forward-viewing and side-viewing scopes
- Indication for defect closure and hemostasis as well as affixing jejunal feeding tubes and esophageal self-expanding metal stents (see complete indications for use for details)



1. Ponugoti PL, Rex DK. Clip retention rates and rates of residual polyp at the base of retained clips on colorectal EMR sites. *Gastrointest Endosc.* 2017;85(3):530-534.

MR Conditional

A patient with this clip can be safely scanned immediately in an MR system that meets the following conditions:

- Static magnetic field of 3.0 or 1.5 T
- Maximum spatial field gradient of 1,900 G/cm (19 T/m)
- Maximum MRI system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg

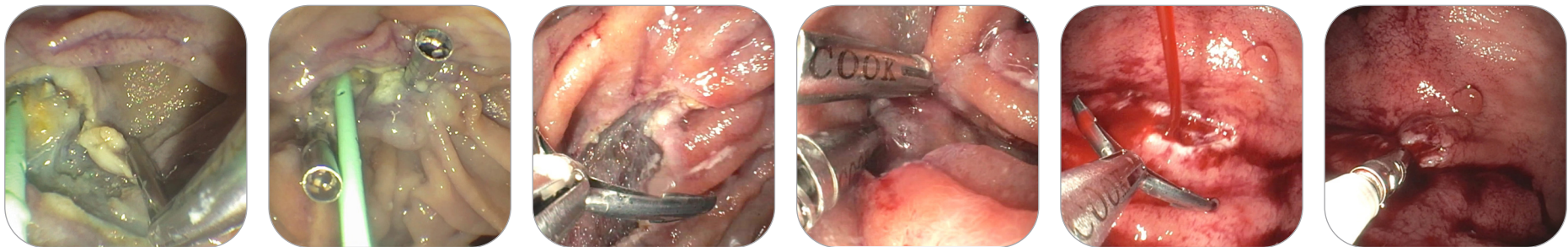
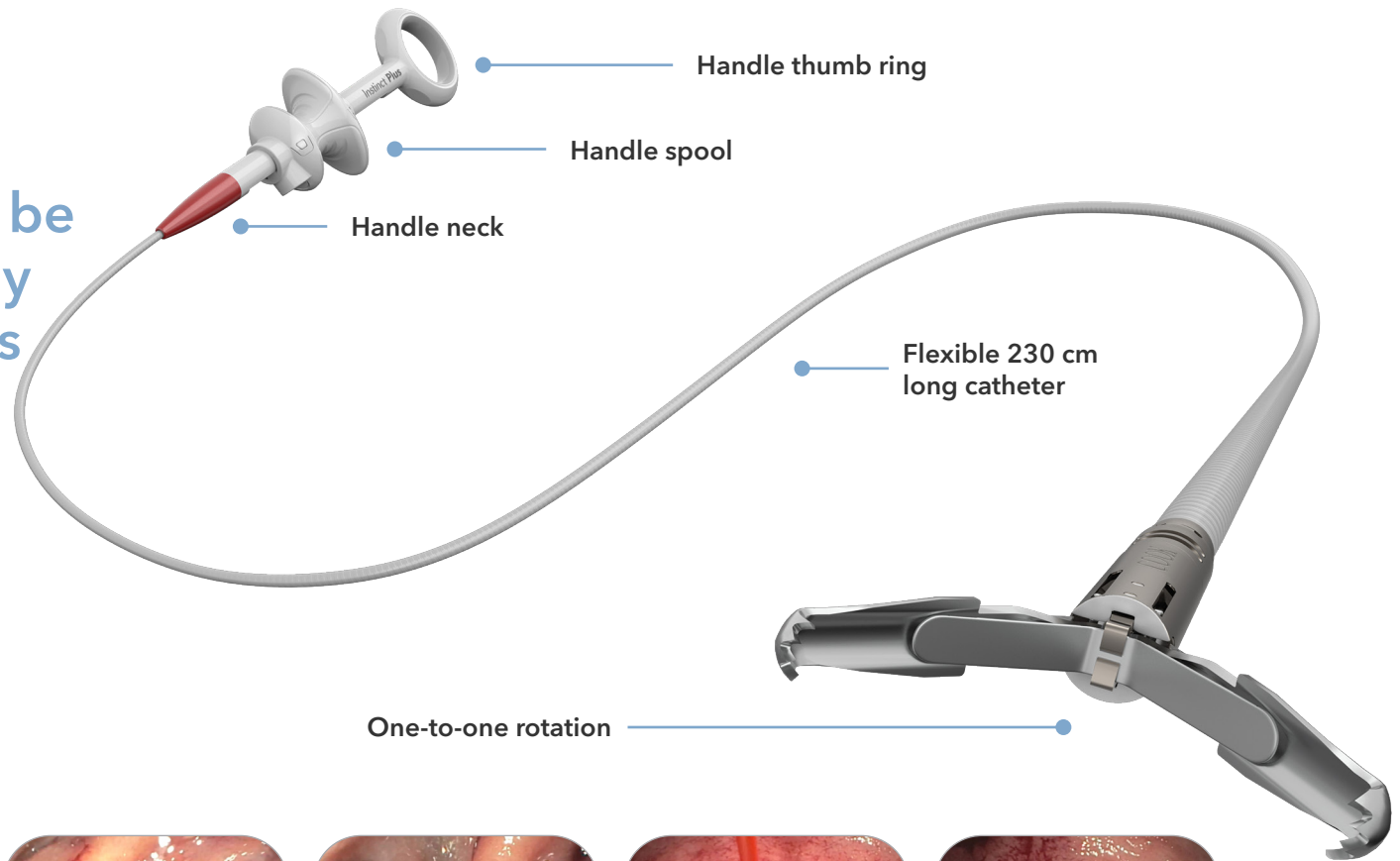


Image credit: Dr. Shou Jiang Tang, the University of Mississippi Medical Center, Jackson, MS

The Instinct Plus Endoscopic Clipping Device is endoscopically placed within the gastrointestinal tract to apply mechanical pressure to tissue and is used for endoscopic clip placement within the gastrointestinal tract for the purpose of:

- Endoscopic marking
- Hemostasis for:
 - › Mucosal/submucosal defects less than 3 cm
 - › Bleeding ulcers
 - › Arteries less than 2 mm
 - › Polyps less than 1.5 cm in diameter
- › Diverticula in the colon, and
- › Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection
- Anchoring to affix jejunal feeding tubes to the wall of the small bowel
- As a supplementary method for closure of GI tract luminal perforations less than 20 mm that can be treated conservatively
- Anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus in patients with fistulas, leaks, perforations, or disunion

Order Number	Reference Part Number	Clip Opening Width mm	Catheter Fr	Catheter Length cm	Quantity	MR Status	Minimum Forward-Viewing Channel Diameter mm	Minimum Side-Viewing Channel Diameter mm
G58010	INSC-P-7-230-S	16	7	230	10	MR Conditional	2.8	4.2

Please follow any step-by-step instructions carefully, including the risk and technical information provided in the IFU. Note that some products or part numbers may not be available in all markets; consult your Cook representative for details.

Instinct Plus® Endoscopic Clipping Device

CAUTION: US federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

INTENDED USE: This device is endoscopically placed within the gastrointestinal tract to apply mechanical pressure to tissue.

INDICATIONS FOR USE: This device is used for endoscopic clip placement within the gastrointestinal tract for the purpose of: 1. Endoscopic marking, 2. Hemostasis for • Mucosal/submucosal defects less than 3 cm, • Bleeding ulcers, • Arteries less than 2 mm, • Polyps less than 1.5 cm in diameter, • Diverticula in the colon, and • Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection. 3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel, 4. As a supplementary method for closure of GI tract luminal perforations less than 20 mm that can be treated conservatively, 5. Anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus in patients with fistulas, leaks, perforations, or disunion.

CONTRAINDICATIONS: Those specific to primary endoscopic procedure to be performed in gaining access to desired site. Those specific to endoscopic hemostasis include: coagulopathy • cricopharyngeal or esophageal narrowing or stricture • tortuous esophagus • uncooperative patient.

WARNINGS: This device has not been evaluated for anchoring to affix fully covered esophageal self-ex-

panding metal stents to the wall of the esophagus in patients with esophageal strictures or malignant obstructions. This device contains nickel which may cause an allergic reaction and other potential systemic complications related to nickel allergy. Additional warnings may be listed in procedural steps below. Do not use this device for any purpose other than stated intended use. **Sterile and Single Use** This device is supplied sterile and designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device contamination with biological or chemical agents and/or mechanical integrity failure of device.

PRECAUTIONS: This device contains cobalt (Co) at a level above 0.1% w/w, which is a substance that is toxic to reproduction and a carcinogen (Class IB). However, the device contains cobalt as a stainless-steel alloy containing cobalt, which does not cause an increased risk of cancer or adverse reproductive effect according to current scientific evidence.

POTENTIAL COMPLICATIONS: Those associated with gastrointestinal endoscopy and endoscopic hemostasis include: allergic reaction to medication • anatomy disruption • aspiration • aspiration pneumonia • cardiac arrhythmia or arrest • fever • hematemesis • hemorrhage • hypotension • infection • migration of clip into the bile duct • minimal acute inflammatory tissue reaction • perforation • respiratory depression or arrest • transient dysphagia • transitory local irritation • wound dehiscence.

See Instructions for Use for full product information.

AB_191002_REV4

Customer Service

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AI, ESC, IR, PI-A4

