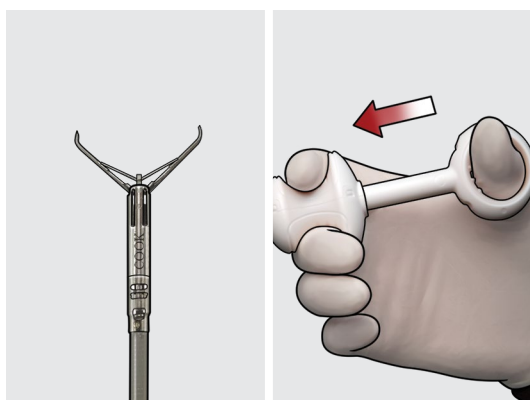


Instinct Plus®

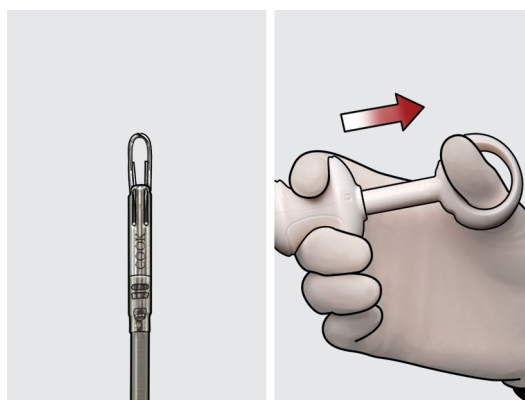
ENDOSCOPIC CLIPPING DEVICE

System Prep 1



Uncoil the device. Verify smooth handle operation and clip action. Open the clip by gently moving the handle spool distally (away from the handle thumb ring). Once the clip is fully open, do not continue advancing the handle spool as the clip may prematurely detach from the catheter.

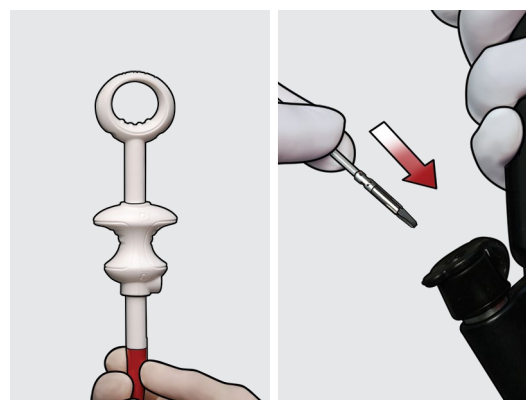
System Prep 2



Close the clip by moving the handle spool proximally until the clip is fully closed.

Caution: Do not continue to pull the handle spool beyond tactile resistance as this may prematurely deploy the clip. Ensure the clip is in the closed position.

Step 1



Visually determine the desired tissue site. With the clip closed, hold the red handle cap and advance the device in small increments into the accessory channel of the endoscope.

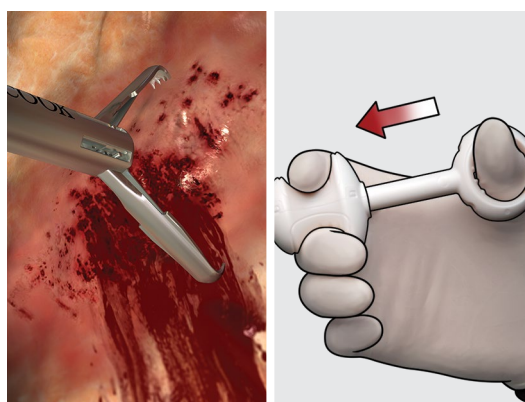
Caution: Holding the handle spool or the handle in a way that prevents handle spool mobility during clip advancement may prematurely deploy the clip.

Step 2



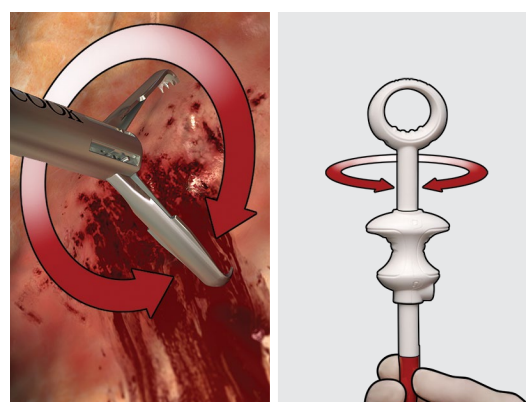
Endoscopically confirm that the device has exited the endoscope. Position the distal tip of the device toward the targeted site.

Step 3



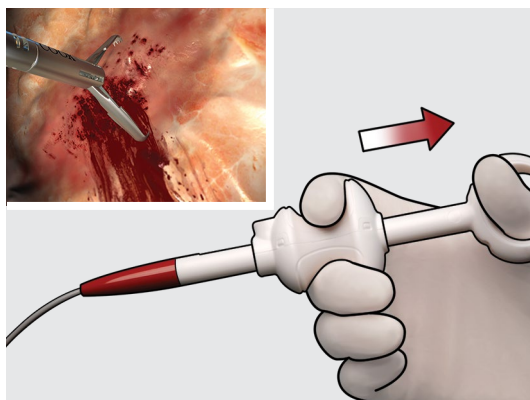
Open the clip and advance the device into contact with the targeted site.

Step 4



The clip can be rotated by turning the handle until the clip is in the proper position.

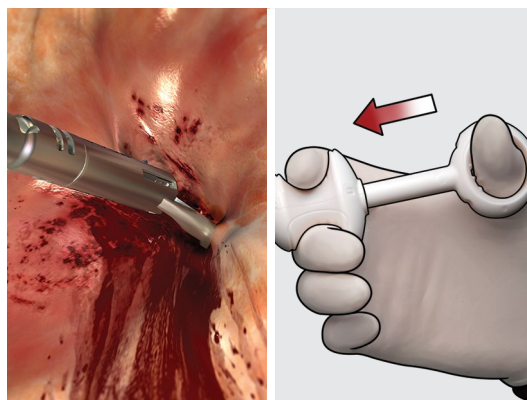
Step 5



Advance the device into contact with the targeted site. When satisfied with clip position, close the clip onto tissue by using slight pressure until tactile resistance is felt.

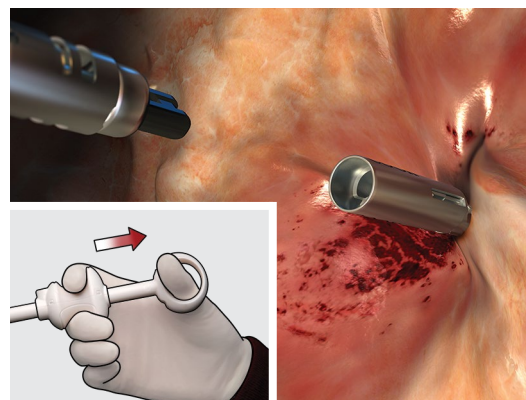
Note: Ensure the clip is not advanced into tissue with excessive force. Avoid clipping onto hard or severely fibrotic tissue. Avoid clipping onto previously deployed clips.

Step 6



Clip position may now be assessed prior to deployment. If the clip is not in the desired position, the clip may be reopened and repositioned up to 5 times.

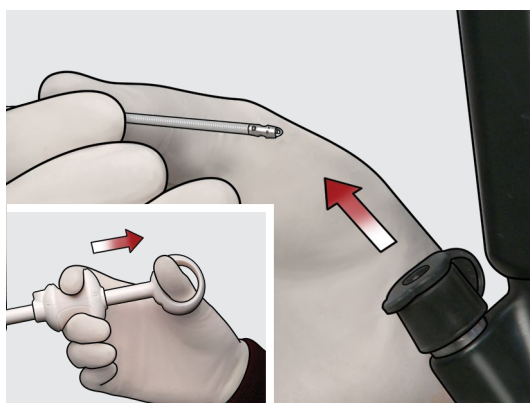
Step 7



To permanently deploy the clip, pull the handle spool toward the handle thumb ring until the clip detaches.

Note: If separation of the clip is not immediate, gently move the catheter back and forth or use other endoscopic maneuvers to separate catheter from clip.

Step 8



This document contains a summary of the Instructions for Use (IFU) but is not a substitute for the IFU. Please refer to the IFU for full prescribing information, warnings, precautions, and potential adverse events.

After clip deployment, continue to apply **slight** pressure on the handle spool as the device is removed from the endoscope.

Warning: Failure to apply slight pressure to the handle during removal can result in tissue damage from the device.

Instinct Plus® Endoscopic Clipping Device

CAUTION: U.S. 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 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, but are not limited to: uncooperative patient, coagulopathy, cricopharyngeal or esophageal narrowing or stricture, and tortuous esophagus.

WARNINGS: This device has not been evaluated for anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus in patients with esophageal strictures or malignant obstructions.

POTENTIAL COMPLICATIONS: Those associated with gastrointestinal endoscopy and endoscopic hemostasis include, but are not limited to: perforation, hemorrhage, aspiration, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest, hematemesis, transient dysphagia, aspiration pneumonia, wound dehiscence, minimal acute inflammatory tissue reaction, transitory local irritation, migration of clip into the bile duct, and anatomy disruption.

See Instructions for Use for full product information.

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