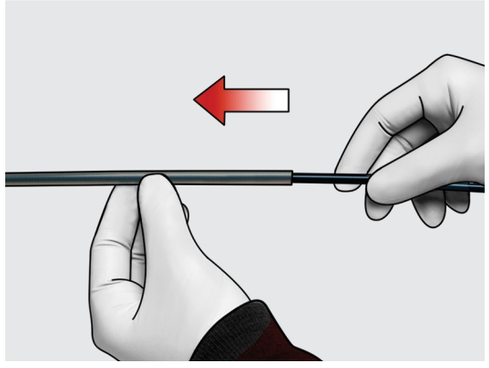
Evolution® Colonic

CONTROLLED-RELEASE STENT - UNCOVERED

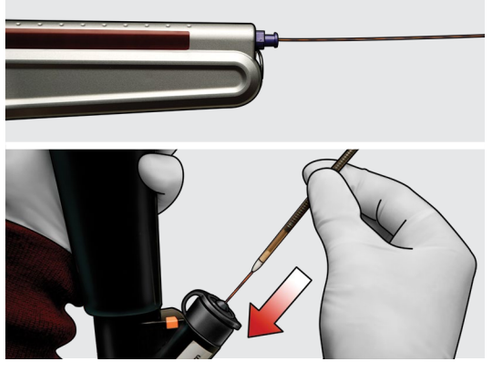
Features

Step 1



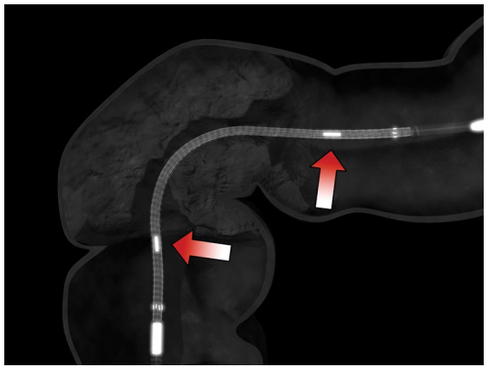
Remove protective tubing from stent.

Step 2



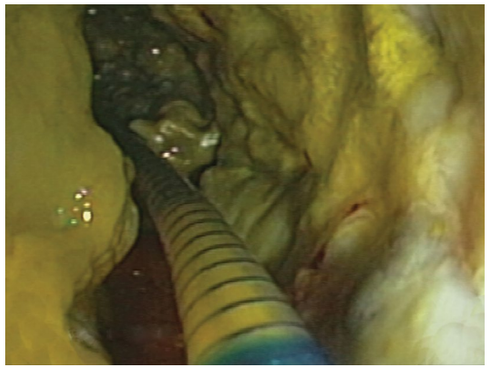
Introduce delivery system in short increments over wire guide, into accessory channel, until it is endoscopically visualized exiting scope.
Note: Minimum accessory channel 3.7 mm

Step 3a



Fluoroscopically position radiopaque markers on inner catheter beyond extremities of stricture to be crossed.

Step 3b

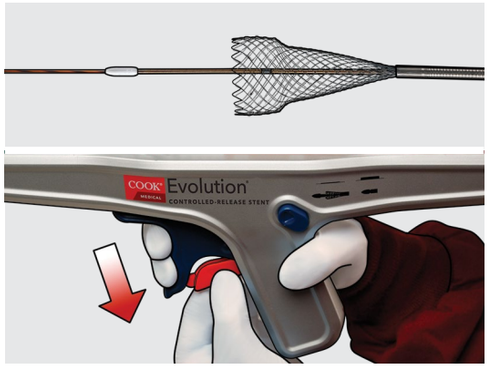


Note: Yellow marker on the delivery system located at proximal end of stent can also serve as an endoscopic/fluoroscopic reference for positioning of the proximal (nearest user) end of the stent relative to the stricture.

COOK® MEDICAL

Image courtesy of Dr. Mario Traina, IsMeTT, Palermo, Italy

Step 4

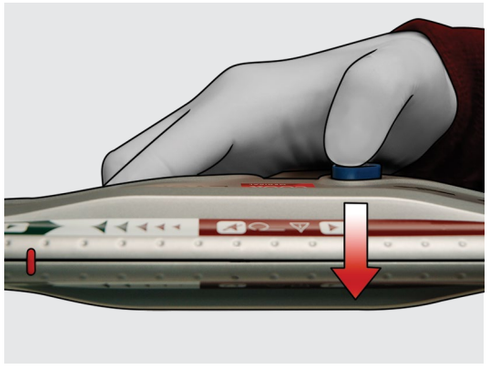


Confirm desired stent position fluoroscopically and deploy stent by removing red safety guard from handle. Continue deploying stent by squeezing trigger.

Step 5a

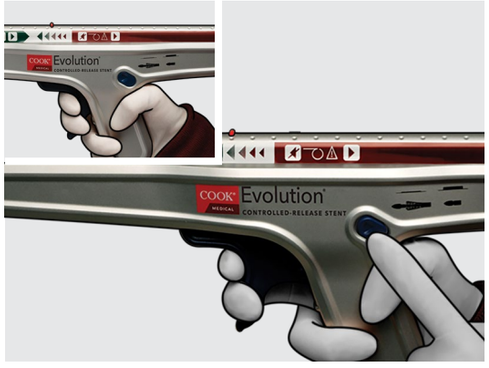
If repositioning is required during deployment, it is possible to recapture stent.
Note: It is not possible to recapture stent after passing point-of-no-return, indicated when the stent deployment indicator on top of introducer has passed point-of-no-return indicator on handle. The stent can be captured a maximum of 5 times.

Step 5b



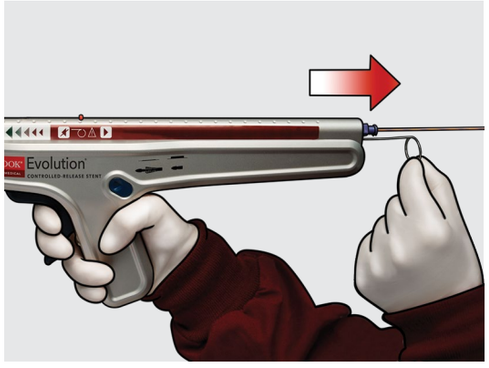
To recapture stent, push directional button on side of delivery system to opposite side.
Note: Hold thumb on button when squeezing trigger for first time to recapture. Continue squeezing trigger as required to recapture stent by desired amount.

Step 6



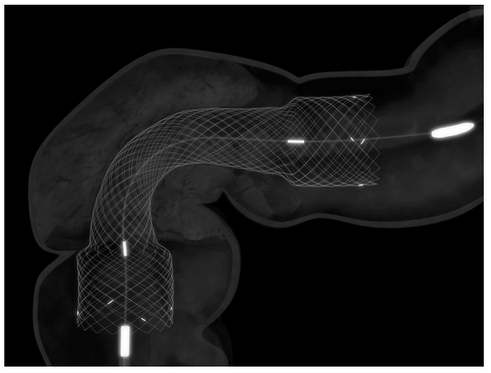
To resume deployment, push directional button to opposite side again and hold button for first stroke while squeezing trigger.

Step 7



When stent point-of-no-return has been passed, pull safety wire out of delivery handle near wire guide port. Continue deploying stent by squeezing trigger.

Step 8



After deployment, fluoroscopically confirm stent expansion. Once expansion is confirmed, introduction system can be safely removed.

Refer to current instructions for detailed system use.

Evolution® Colonic Stent System – Uncovered

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 palliative treatment of colonic obstruction or colonic strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

CONTRAINDICATIONS: Those specific to GI endoscopy and any procedure to be performed in conjunction with stent placement. • Additional contraindications include, but are not limited to: enteral ischemia, suspected or impending perforation, intra-abdominal abscess/perforation, inability to pass wire guide or stent through obstructed area, patients for whom endoscopic procedures are contraindicated, significant coagulopathy, benign disease.

WARNINGS: The stent is not intended to be removed or repositioned after stent placement and is intended to remain in the body permanently. Attempts to remove or reposition stent after placement may cause damage to surrounding tissue or mucosa. Stent cannot be retrieved after the deployment threshold has been passed. Corresponding marks on outer catheter and delivery handle indicate when threshold has been passed. • This stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity. • To minimize pain and tenesmus, the stent end nearest to the anal canal/anus should be placed 2 cm above the anal canal or 6 cm from the anus. • The device should be used with caution and only after careful consideration in patients with: - Patients with radiation colitis or proctitis. - Patients with elevated bleeding times, coagulopathies.

PRECAUTIONS: Refer to product package label for the minimum channel size required for this device. • A complete diagnostic evaluation must be performed prior to use to determine proper stent size. • If wire guide or stent cannot advance through obstructed area, do not attempt to place stent. • Stent should be placed endoscopically with fluoroscopic monitoring. • The stent should only be placed with the Cook delivery system, which is provided with each stent. • This device is intended for palliative treatment only. Alternate methods of therapy should be investigated prior to placement. • After stent placement, alternative methods of treatment such as chemotherapy and radiation should not be administered as this may increase risk of stent migration due to tumor shrinkage, stent erosion, and/or mucosal bleeding. • Long-term patency of this device has not been established. Periodic evaluation is advised.

POTENTIAL COMPLICATIONS: Those associated with GI endoscopy include, but are not limited to: perforation, hemorrhage, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest. • Additional complications include, but are not limited to: intestinal perforation, pain, inadequate Stent expansion, stent misplacement and/or migration, tumor ingrowth or overgrowth, stent occlusion, ulcerations, pressure necrosis, erosion of the luminal mucosa, septicemia, foreign body sensation, bowel impaction, diarrhea, constipation, peritonitis, symptoms of tenesmus or urgency/incontinence, death (other than due to normal disease progression).

See Instructions for Use for full product information.

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