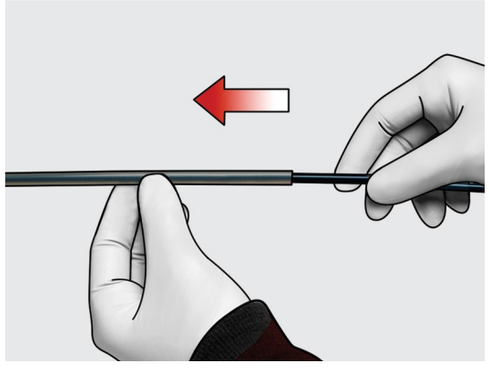
Evolution® Duodenal

CONTROLLED-RELEASE STENT - UNCOVERED

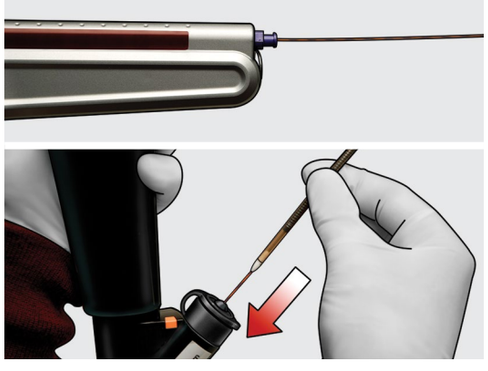
Features

Step 1



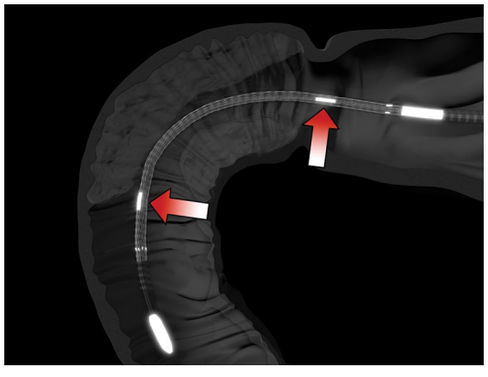
Remove stent delivery system from the package.

Step 2



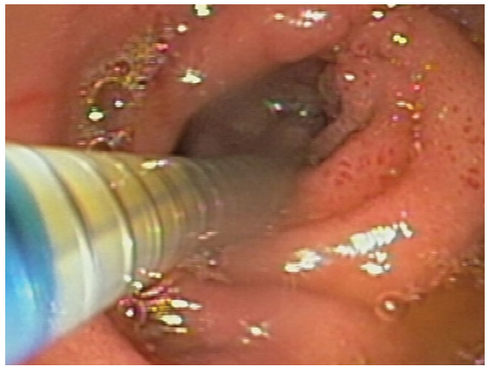
Introduce the delivery system in short increments over the wire guide, into the accessory channel, until it is endoscopically visualized exiting the scope. **NOTE:** The minimum accessory channel size is 3.7 mm.

Step 3a



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

Step 3b



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

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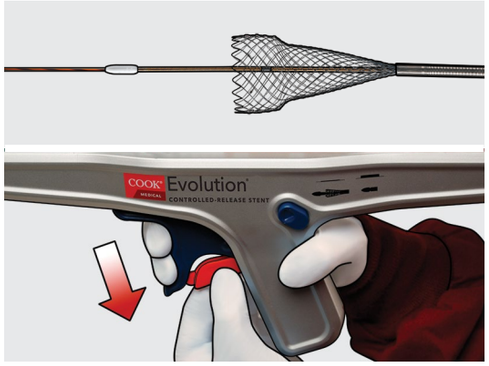
Step 3b image courtesy of Dr. Mario Traina, IsMeTT, Palermo, Italy

Step 4

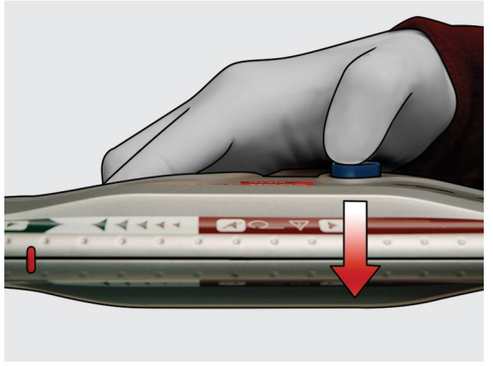


Confirm the desired stent position fluoroscopically and deploy the stent by removing the red safety guard from the handle. Continue deploying the stent by squeezing the trigger.

Step 5a

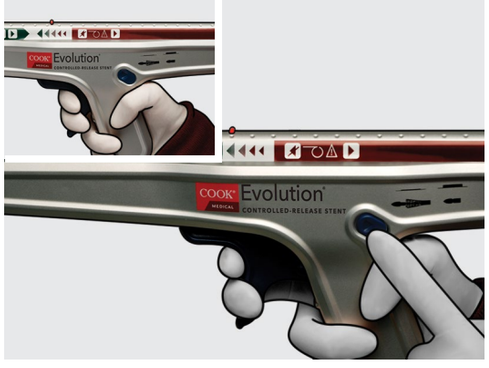
If repositioning is required during deployment, it is possible to recapture the stent.
NOTE: It is not possible to recapture the stent after passing the point of no return, indicated when red marker on top of the handle has passed the point-of-no-return position on the handle label. The stent can be recaptured a maximum of 5 times.

Step 5b



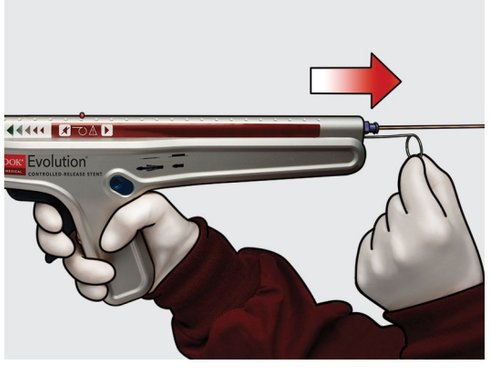
To recapture the stent, push the directional button on the side of the delivery system to the opposite side.
NOTE: Hold your thumb on the button when squeezing the trigger for the first time to recapture the stent. Continue squeezing the trigger as required to recapture the stent by the desired amount.

Step 6



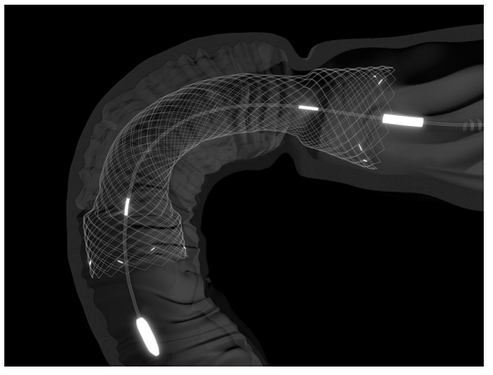
To resume deployment, push the directional button to the opposite side again and hold the button for the first stroke while squeezing the trigger.

Step 7



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

Step 8



After deploying the stent, fluoroscopically confirm that the stent has expanded. Once the expansion has been confirmed, the delivery system can be safely removed.

Refer to the current Instructions for Use for detailed system use.

Evolution® Duodenal Stent System – Uncovered

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

INTENDED USE: This device is used for palliative treatment of duodenal or gastric outlet obstruction and duodenal strictures caused by malignant neoplasms.

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 • coagulopathy/patients with elevated bleeding times • 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. The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity. This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease. If package is opened or damaged when received, do not use. Visually inspect with particular attention to kinks, bends and breaks. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify Cook for return authorization. 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.

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 using fluoroscopic monitoring with endoscopy. 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. Long-term patency of this device has not been established. Periodic evaluation is advised. Stent cannot be retrieved after the deployment threshold has been passed. The position of the red marker on the top of the handle in relation to the point-of-no-return position on the handle label indicates when threshold has been passed. Do not use this device for any purpose other than stated intended use. Use of this device is restricted to a trained healthcare professional.

POTENTIAL ADVERSE EVENTS: Potential adverse events associated with GI endoscopy include, but are not limited to: airway obstruction • allergic reaction to contrast or medication • aspiration • biliary obstruction • cardiac arrhythmia or arrest • cholangitis • fever • hemorrhage • hypotension • infection • perforation • reflux • respiratory depression or arrest. Additional adverse events include, but are not limited to: allergic reaction to nickel • bowel impaction • death (other than due to normal disease progression) • erosion of the luminal mucosa • foreign body sensation • inadequate expansion • intestinal perforation • nausea/vomiting • pain/discomfort • pancreatitis • pressure necrosis • septicemia • stent misplacement and/or migration • stent occlusion • tumor ingrowth or overgrowth • ulcerations.

See Instructions for Use for full product information.

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COOK MEDICAL

USA Website: cookmedical.com
EDI: cookmedical.com/edi.do
Americas:
Phone: +1 812.339.2235, 800.457.4500, Fax: 800.554.8335
E-mail: orders@cookmedical.com