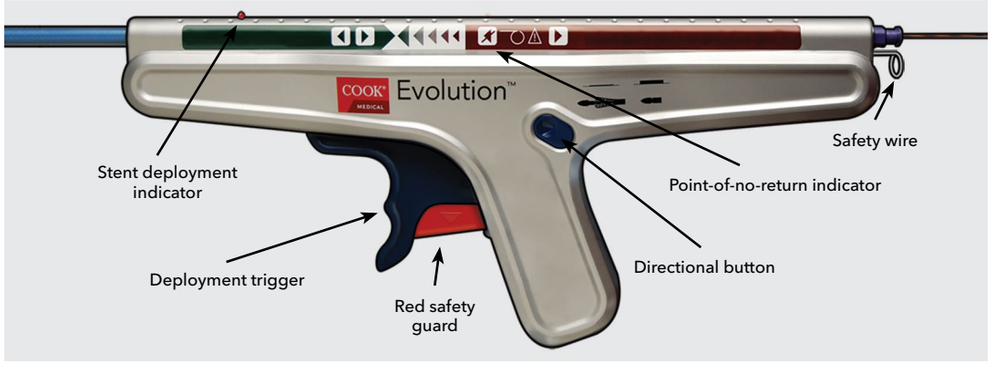
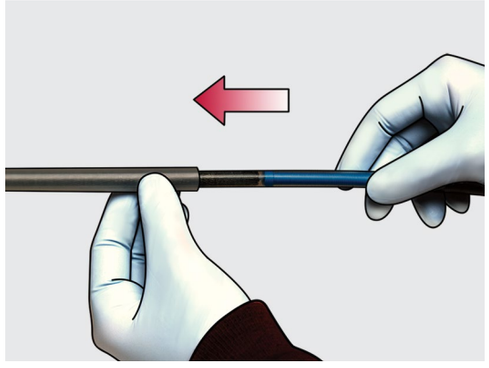
Evolution® Esophageal

CONTROLLED-RELEASE STENT

Features

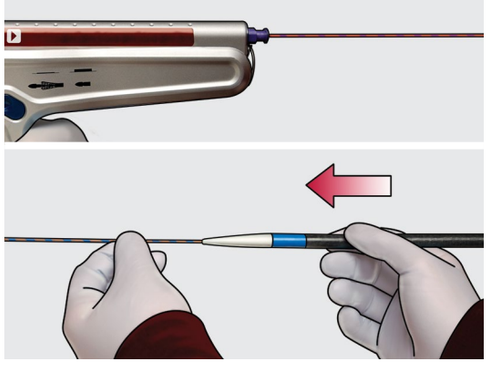


Step 1



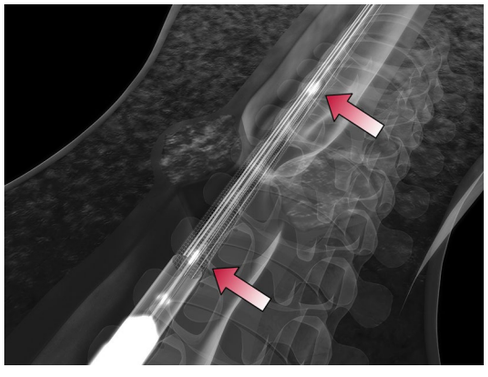
Remove the protective tubing from the stent.

Step 2



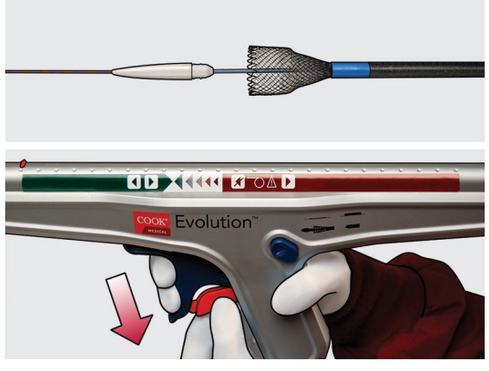
Using fluoroscopic guidance, introduce and advance the introduction system in short increments over the pre-positioned wire guide into the esophagus.

Step 3



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

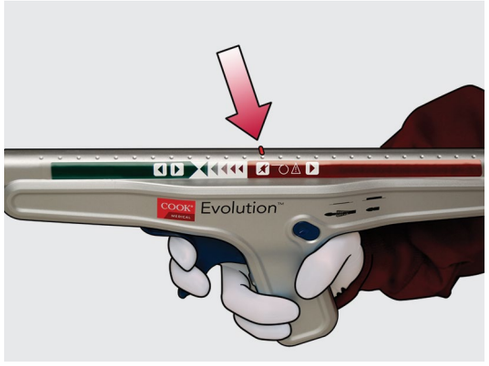
Step 4



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

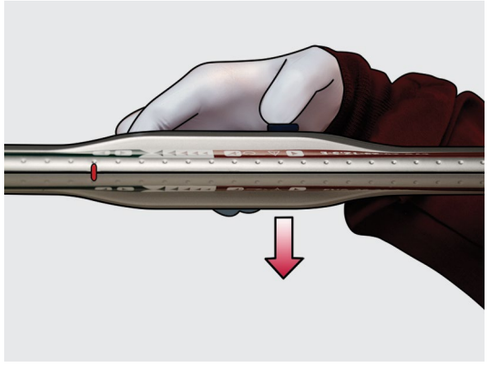
COOK® MEDICAL

Step 5a



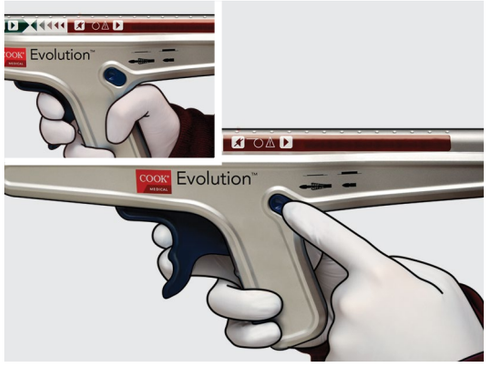
In case you need to reposition the stent while you are deploying it, it is possible to recapture it.
Note: It is not possible to recapture the stent after you have passed the point of no return, indicated when the stent deployment indicator on the top of the introducer has passed the point-of-no-return indicator on the handle.

Step 5b



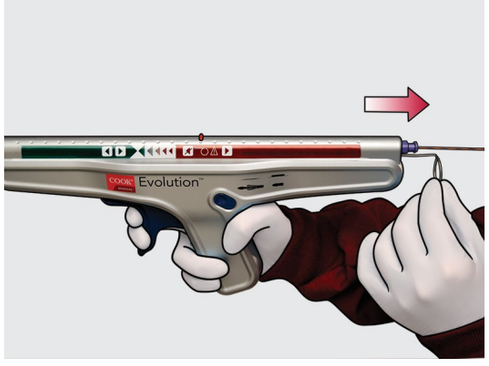
To recapture the stent, push the directional button on one side of the delivery system to the opposite side.
Note: Hold your thumb on the button when squeezing the trigger for the first time to recapture the stent. Continue squeezing the trigger as required to recapture the stent by desired amount.

Step 5c



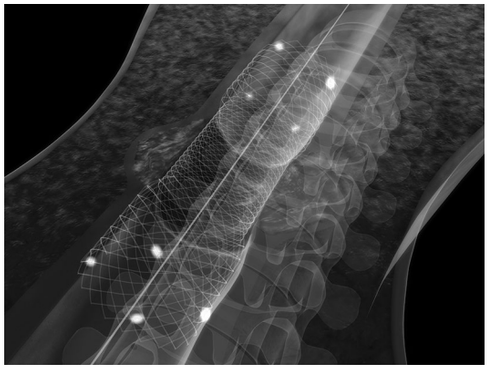
To resume deployment of the stent, push the directional button to the opposite side again, and hold the button for the first stroke while squeezing the trigger.

Step 6



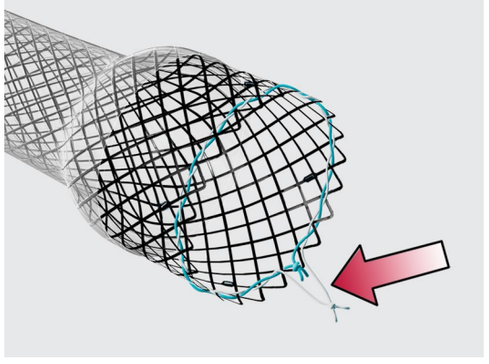
When the point of no return has been passed, pull the safety wire out of the delivery handle near the wire guide port. Continue deploying the stent by squeezing trigger.

Step 7



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

Step 8



With the white lasso on proximal end of stent you can reposition stent, directly after placement by pulling with forceps on the white lasso and reposition stent to desired area.
Note for FC: To reposition stent directly after placement, grip either the proximal-end lasso or the distal-end lasso with forceps and reposition stent to desired area.

Evolution® Esophageal Stent System – Partially Covered / Fully Covered

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 to maintain patency of malignant esophageal strictures and/or to seal tracheoesophageal fistulas.

CONTRAINDICATIONS: Those specific to upper GI endoscopy and any procedure to be performed in conjunction with stent placement. Additional contraindications include, but are not limited to: total esophageal obstruction • strictures that cannot be dilated to a minimum size as outlined in the precautions section • placement requiring positioning of stent within 2 cm of the cricopharynx • surgical resection candidates • hiatal hernia and gastric prolapse in the esophageal area • patients with a perforated esophagus • placement in actively bleeding tumors • benign diseases. Relative contraindications include, but are not limited to: uncooperative patient • coagulopathy • tracheal compression • recent myocardial infarction • cervical arthritis with fixed cervical spine • large tumor mass occupying the mediastinum • nonobstructive tumor • gastric outlet obstruction • necrotic esophageal mucosa • acutely angled stenosis.

WARNINGS: The **stent is not intended to be removed** and is considered a permanent implant. Attempts to remove stent after placement may cause damage to esophageal mucosa. 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 product with particular attention to kinks, bends and breaks. If an abnormality is detected that would prohibit proper working conditions, do not use. Please notify Cook for return authorization. This stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity. Do not introduce the endoscope into the stent as displacement may occur. 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. The risk of perforation and erosion into adjacent vascular structures or aortoespohageal and arterioesophageal fistulas may be increased with pre- or post-operative chemotherapy and radiation, longer implantation times, aberrant anatomy, and/or mediastinal contamination or inflammation.

PRECAUTIONS: A complete diagnostic evaluation must be performed prior to use to determine proper stent size. Part numbers with the prefix EVO-FC are Fully Covered. Stent should be placed using fluoroscopic monitoring. Stent should only be placed with the Cook delivery system, which is provided with each stent. **Note:** Prior to advancing system, area to be stented should be dilated to: **For (18mm x 23mm) stent** – a minimum of 9 mm and a maximum of 11 mm. If area is dilated greater than 11 mm, stent may migrate. **For (20mm x 25mm) stent** – a minimum of 10 mm and a maximum of 14 mm. If area is dilated greater than 14 mm, stent may migrate. 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. This device shortens upon deployment. With proximal strictures near the upper esophageal sphincter, deployment should be performed under fluoroscopic visualization as this may enhance placement accuracy. Do not use this device for any purpose other than stated intended use. Stent cannot be retrieved after the deployment threshold has been passed. The position of the red marker on top of the handle in relation to the point-of-no-return position on the handle label indicates when the threshold has been passed. Use of this device is restricted to a trained healthcare professional.

POTENTIAL ADVERSE EVENTS: Those associated with upper GI endoscopy include, but are not limited to: allergic reaction to contrast or medication • aspiration • cardiac arrhythmia or arrest • fever • hemorrhage • hypotension • infection • perforation • reflux • respiratory depression or arrest • vomiting. Additional adverse events include, but are not limited to: airway compression • allergic reaction to nickel • aortoesophageal fistula and arterioesophageal fistula • chest or retrosternal pain • death (other than due to normal disease progression) • dysphagia • edema • erosion or perforation of stent into adjacent vascular structures • esophageal ulceration and erosion • esophagitis • fistula involving trachea, bronchi or pleural space • food bolus impaction • foreign body sensation or reaction • gas bloat • inadequate stent expansion • intestinal obstruction secondary to migration • mediastinitis or peritonitis • nausea • pain/discomfort • reocclusion • sensitivity to metal components • sepsis • stent misplacement and/or migration • tracheal obstruction • tumor ingrowth or overgrowth • wire entrapment.

See Instructions for Use for full product information.

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COOK MEDICAL

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Refer to current instructions for detailed system use.