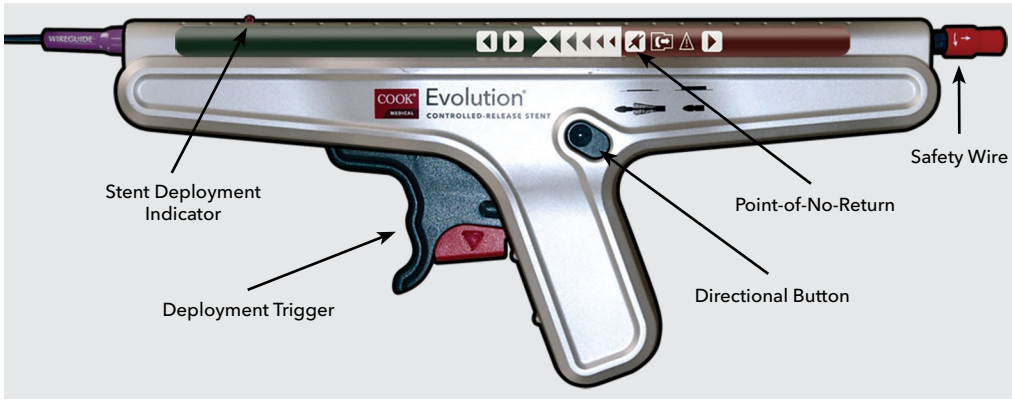
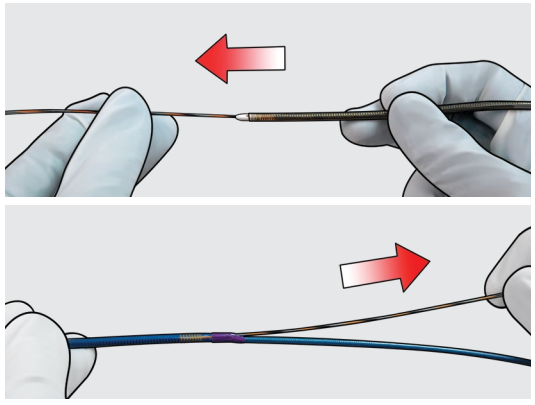
Evolution® Biliary

CONTROLLED-RELEASE STENT

Features

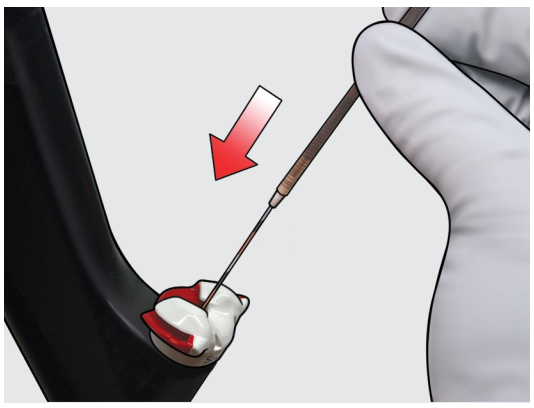


Step 1



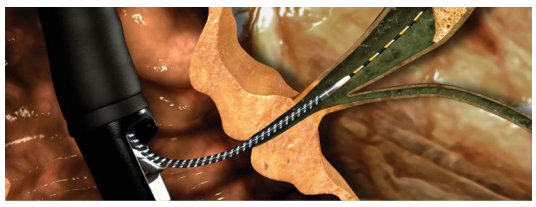
Backload device over a prepositioned wire guide, ensuring the wire guide exits catheter at zip port.

Step 2



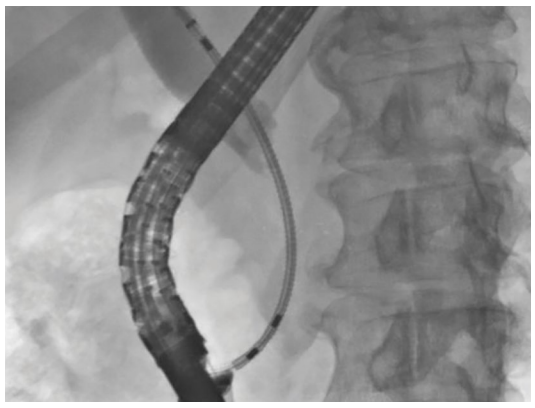
Unlock wire guide from locking device and introduce device in short increments until zip port is inside of accessory channel of the duodenoscope; then relock wire guide. Continue advancing device in short increments.

Step 3



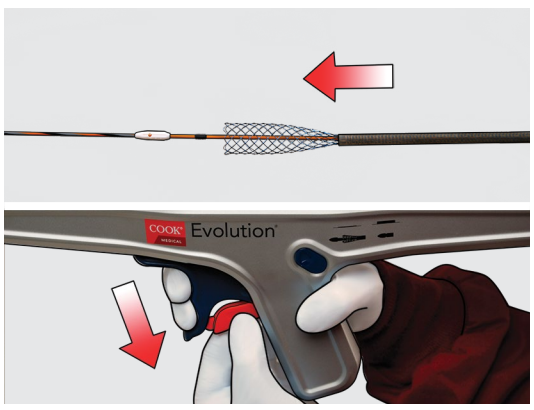
With elevator open, advance device until endoscopically visualized exiting duodenoscope. For transpapillary placement, reference the yellow marker for accurate stent positioning. **Note:** Stents bridging papilla should extend beyond papilla and into duodenum approximately 0.5 cm after deployment.

Step 4



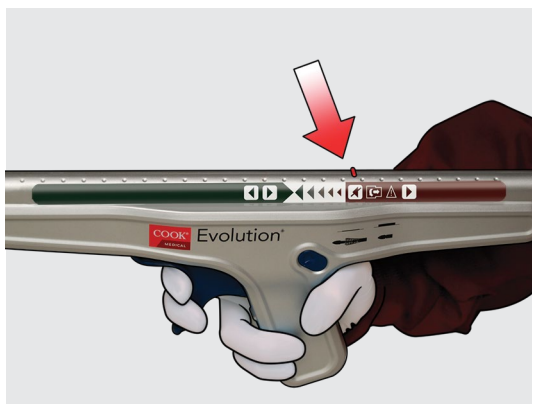
Under fluoroscopic guidance with elevator open, continue to advance the device in short increments until the stent is visualized through the stricture. Fluoroscopically visualize radiopaque markers on inner catheter (2 and 4 on image of Step 6b below) at either end of the stent, and position the radiopaque markers a minimum of 1 cm beyond the stricture so that the stent bridges the stricture completely.

Step 5



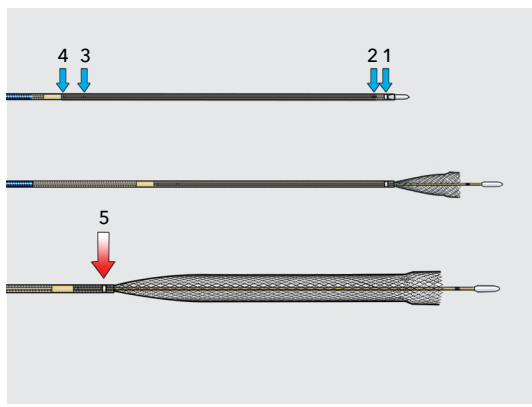
Confirm desired stent position fluoroscopically. To deploy stent, remove red safety guard from handle; then squeeze trigger. Continue deploying stent by squeezing trigger.

Step 6a



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 red marker on top of the handle has passed the point-of-no-return position on the handle label.

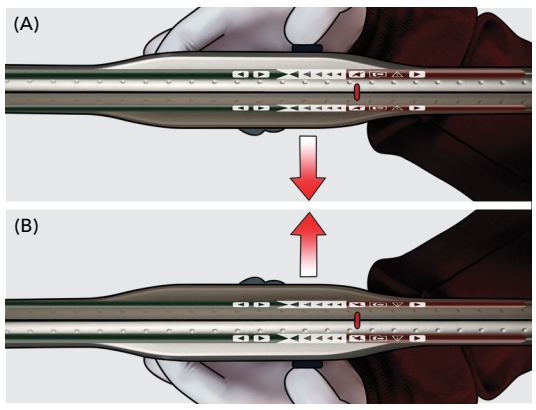
Step 6b



If you are fluoroscopically monitoring the point-of-no-return (5), the stent can be recaptured until the point where the outer catheter radiopaque marker (1) is aligned with the second internal catheter radiopaque marker (3). **Note:** It is **not** possible to recapture the stent after the outer catheter radiopaque marker passes the second inner catheter radiopaque marker. **Note:** The stent can be recaptured a maximum of three times.

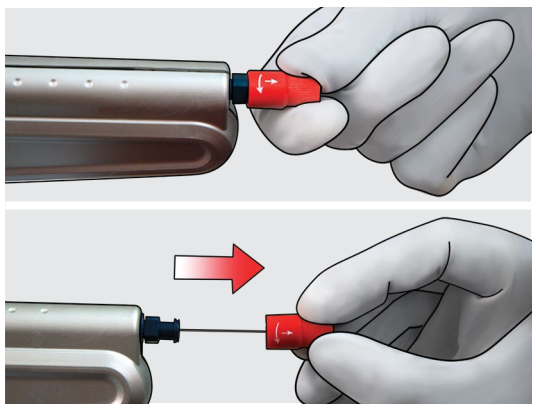
COOK MEDICAL

Step 7



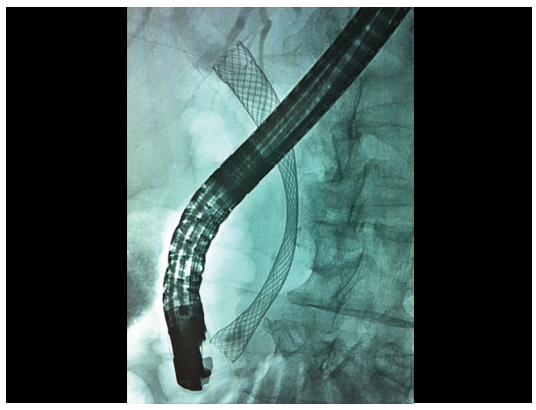
(A) To reposition the stent, you must first recapture the stent and ensure the elevator is open. **Note:** Do not push forward on the delivery system with the stent partially deployed. Push directional button on side of delivery handle to opposite side. **Note:** Hold thumb on button when squeezing trigger for first time to recapture the stent. Continue squeezing trigger as required to recapture the stent by desired amount. (B) To resume deployment, push directional button to opposite side and hold button for first stroke while squeezing trigger.

Step 8



When stent point-of-no-return has been passed, disconnect Luer lock fitting and remove safety wire completely from delivery handle. Continue deploying stent by squeezing trigger.

Step 9



After deployment, fluoroscopically confirm stent expansion. While maintaining wire guide position, push direction button to the opposite side. Squeeze the trigger to completely recapture the delivery system. Unlock the wire guide from wire guide locking device. Remove wire guide and introduction system from duodenoscope with elevator fully down.

Refer to current instructions for detailed system use.

Evolution® Biliary 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 in palliation of malignant neoplasms in the biliary tree.

CONTRAINDICATIONS: Those specific to ERCP and any procedure to be performed in conjunction with stent placement. Additional contraindications include, but are not limited to: inability to pass the wire guide or stent through the obstructed area • biliary duct strictures of benign etiology • biliary obstruction preventing endoscopic cholangiography • concurrent perforated bile duct • those patients for whom endoscopic procedures are contraindicated • patients with coagulopathy, concurrent bile duct stones, very small intrahepatic ducts and any use other than those specifically outlined under Intended Use.

WARNINGS: The safety and effectiveness of this device for use in the vascular system has not been established. This device is not intended to be deployed through the wall of a previously placed or existing metal stent. Doing so could result in difficulty or inability to remove introducer. The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity. This stent system is designed for single use only. Attempts to reprocess, resterilize and/or reuse may lead to device failure and/or transmission of disease. If the 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, additional methods of treatment such as chemotherapy and irradiation may increase the risk of stent migration due to tumor shrinkage, stent erosion, and/or mucosal bleeding. **This metal biliary stent is not intended to be repositioned or removed after stent placement** and is considered a permanent implant. Attempts to remove the stent after placement may cause damage to the surrounding mucosa. In case of accidental deployment or improper placement (immediately following deployment), stent should be left in place and placement of a second stent of the same diameter should be attempted to achieve desired result providing adequate overlapping (minimum 1cm).

PRECAUTIONS: Refer to the package label for the minimum channel size required for this device. A complete diagnostic evaluation should be performed prior to placement to measure the stricture length and determine the proper stent length. The stent length chosen should allow for additional length on either side of the stricture. **Note:** In the event a single stent will not adequately cover the stricture, a second stent of the same diameter should be placed providing adequate overlapping (minimum 1cm) of the initially placed stent to ensure a bridging of the stricture between the stents. If wire guide or stent cannot advance through obstructed area, do not attempt to place stent. Stent should be placed using fluoroscopic and endoscopic monitoring. The stent should only be placed with the Cook delivery system, which is provided with each stent. This stent is intended for palliative treatment only. Alternate methods of therapy should be investigated prior to placement. Long-term patency with this stent has not been established. Periodic evaluation of the stent is advised. Assessment must be made to determine the necessity of sphincterotomy or balloon dilation prior to stent placement. In the event sphincterotomy or balloon dilation is required, all appropriate cautions, warnings and contraindications must be observed. Stent cannot be recaptured after the deployment threshold has been passed. The position of the red marker on the top of the handle in relation to point-of-no-return position on the handle label indicates when threshold has been passed. Do not attempt to reload a deployed stent. Do not use this device for any other purpose than the stated intended use. Not compatible with THSF wire guide. Use of this device is restricted to a trained healthcare professional. Passing a delivery system through a just deployed stent may cause a previously placed stent to dislodge. To reduce the risk of stent dislodgement ensure that the delivery system is completely recaptured following stent deployment.

POTENTIAL ADVERSE EVENTS: Potential adverse events associated with ERCP include, but are not limited to: allergic reaction to contrast or medication • aspiration • cardiac arrhythmia or arrest • cholangitis • cholecystitis • cholestasis • hemorrhage • hypotension • infection • pancreatitis • perforation • respiratory depression or arrest • sepsis. Additional adverse events that can occur in conjunction with biliary stent placement include, but are not limited to: allergic reaction to nickel • bile duct ulceration • death (other than due to normal disease progression) • fever • inflammation • ingrowth due to tumor or excessive hyperplastic tissue • nausea • obstruction of the pancreatic duct • pain/discomfort • perforation • recurrent obstructive jaundice • stent migration • stent misplacement • stent occlusion • trauma to the biliary tract or duodenum • tumor overgrowth • vomiting.

See Instructions for Use for full product information.

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Image in Step 3 courtesy of Prof. Horst Neuhaus
EVK, Düsseldorf, Germany.

Images in Step 4 and 9 courtesy of Prof. Marco Bruno
Erasmus Medical Centre, Rotterdam, the Netherlands.

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