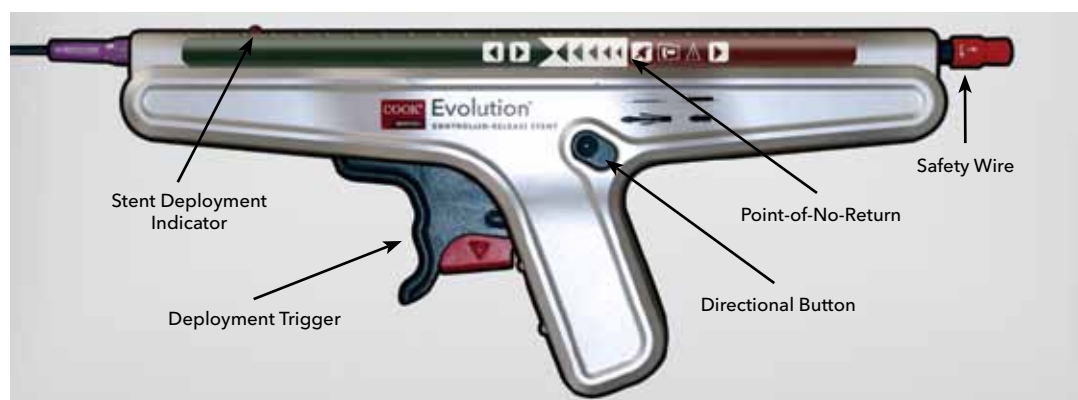


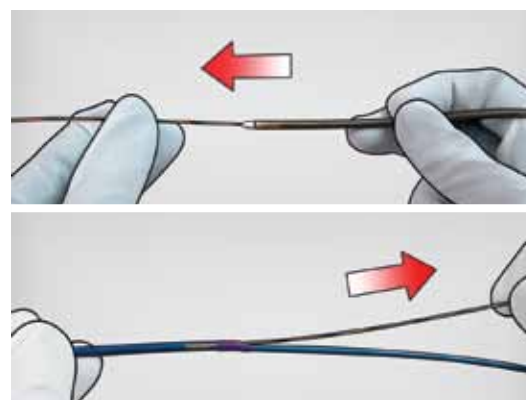
Evolution® Biliary

CONTROLLED-RELEASE STENT

Features



Step 1



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

Step 2



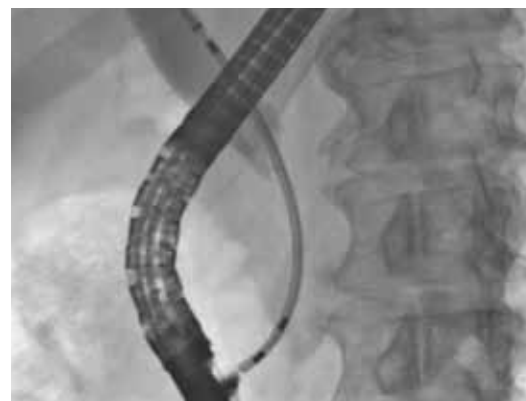
Unlock wire guide from locking device and introduce device in short increments until zip port is inside of accessory channel, then relock wire guide. Continue advancing device in short increments.

Step 3



With elevator open, advance device until endoscopically visualized exiting endoscope. 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



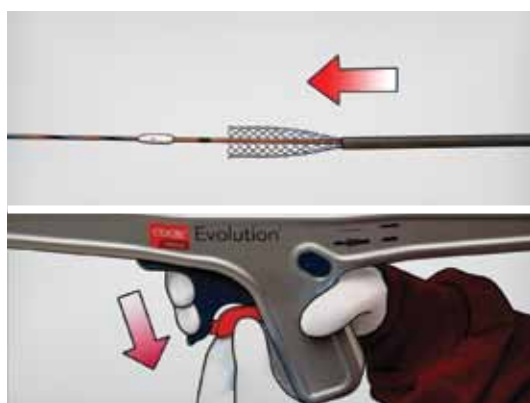
Under fluoroscopic guidance with elevator open, continue to advance device until the stent is visualized through the stricture. Fluoroscopically visualize radiopaque markers on either end of the stent and position the radiopaque markers a minimum of 1 cm beyond the stricture.

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

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

Warning: The safety and effectiveness of this device for use in the vascular system have not been established.

Step 5



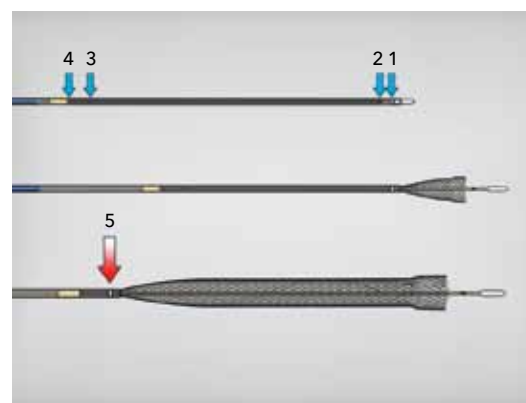
Confirm desired stent position. To deploy stent, remove red safety guard from handle then squeeze trigger. Continue deploying stent by squeezing trigger.

Step 6a



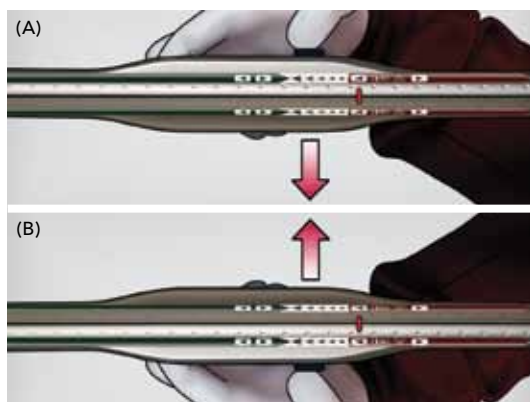
If repositioning is required during deployment, it is possible to recapture stent. **Note:** It is **not** possible to recapture stent after passing point-of-no-return, indicated when the red marker on top of the handle has passed the point-of-no-return on handle label.

Step 6b



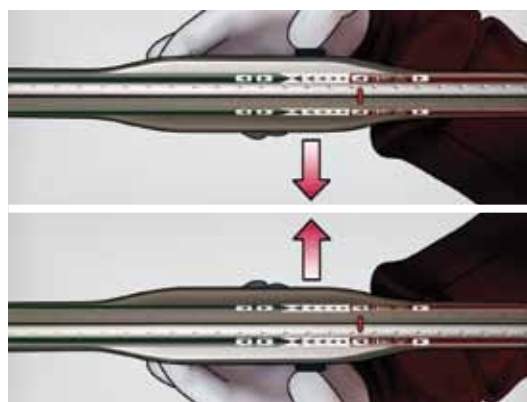
If fluoroscopically monitoring the point-of-no-return, the stent can be recaptured until the point where the external catheter radiopaque marker is aligned with the second internal catheter radiopaque marker. **Note:** It is **not** possible to recapture stent after the outer catheter radiopaque marker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

Step 7



(A) To recapture stent the elevator must be open, 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. (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 introduction system. Remove wire guide and introduction system from endoscope with elevator fully down.

Refer to current instructions for detailed system use.

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