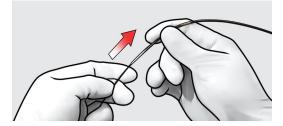
Zilver 635[®] Biliary

SELF-EXPANDING STENT

Wire guide Red safety lock Stent lumen port (cap) Wire guide hub Handle Stent radiopaque markers Stent radiopaque markers Stent radiopaque marker Tip Tip

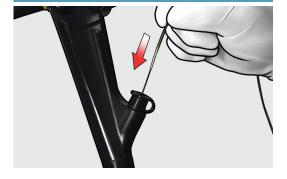
NOTE: For side-by-side stenting, a duodenoscope with a minimum accessory channel diameter of 4.2 mm is required.

Step 1



NOTE: For the best results, keep the wire guides wet. Unlock the wire guide, if using a wire guide locking device. Backload the device over the pre-positioned wire guide, ensuring the wire guide exits the wire guide hub.

Step 2a



Introduce the device in short increments into the accessory channel of the duodenoscope.

Step 3a



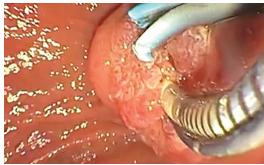


Step 3b



Repeat steps 1-3a for the second device in the case of side-by-side stenting. **NOTE:** Both devices must be in position prior to the deployment of either stent.

Step 2b

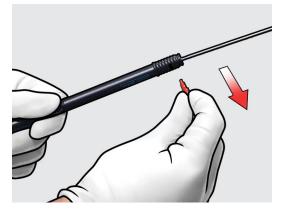


With the elevator open, continue advancing the device in short increments until it is endoscopically visualised exiting the duodenoscope.

Under fluoroscopic guidance, with the elevator open, pass the stent delivery system through the papilla and into the common bile duct. Advance the device in short increments until the stent's position is fluoroscopically visualised through the stricture. Confirm the desired stent position fluoroscopically. **NOTE:** For transpapillary placement, reference the yellow endoscopic marker for stent positioning. A stent bridging the papilla should extend beyond the papilla and into the duodenum approximately 0.5 cm after deployment.

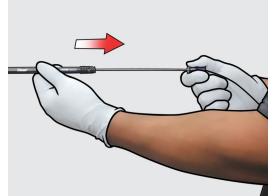


Step 4



Prior to deploying the stent(s), remove the red safety lock(s). NOTE: Ensure that the red safety lock is not inadvertently removed prior to this step.

Step 5



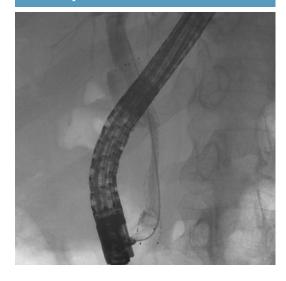
Under fluoroscopic guidance, with the elevator open, begin deployment of the stent(s) by holding the wire guide hub(s) stationary and slowly pulling back on the handle(s). Simultaneously maintain each stent's position during deployment by withdrawing the delivery system(s) from the duodenoscope.

Step 6



Continue simultaneously pulling back on the handle(s) and withdrawing the delivery system(s) until you fluoroscopically confirm that each stent has been completely deployed. For transpapillary placement, endoscopic confirmation of complete stent deployment may also be used.

Step 7



While maintaining the wire guide's position, with the elevator open, carefully remove the delivery system from within the expanded stent. Remove the delivery system from the duodenoscope while monitoring the position of the stent fluoroscopically. NOTE: Fluoroscopically ensure that the stent has expanded sufficiently to allow for the safe removal of the tip. NOTE: Repeat this step if necessary for the removal of a second delivery system.

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Please see product risk information in the IFU at cookmedical.eu.

Image in Step 2b courtesy of Dr Gregory Ginsberg, Hospital of the University of Pennsylvania, United States. Image in Step 3a courtesy of Dr Mohan J. Ramchandani, AIG Hospitals, Gachibowli, India. Image in Step 7 courtesy of Dr Sundeep Lakhtakia, AIG Hospitals, Gachibowli, India.

