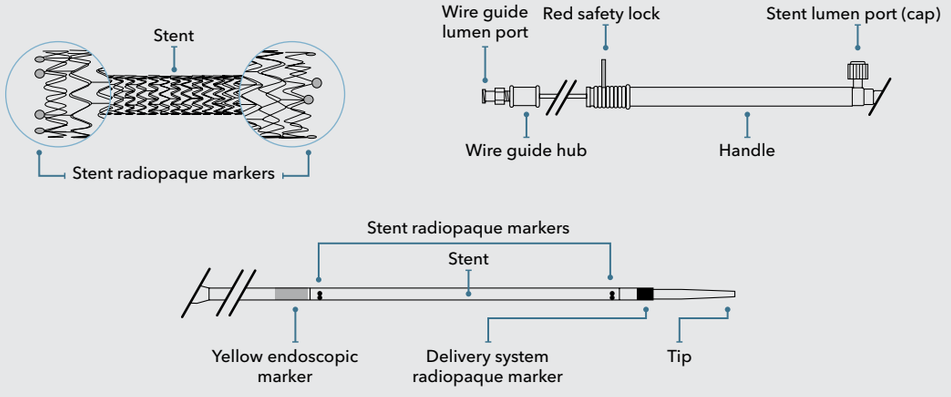
Zilver 635® Biliary

STENT

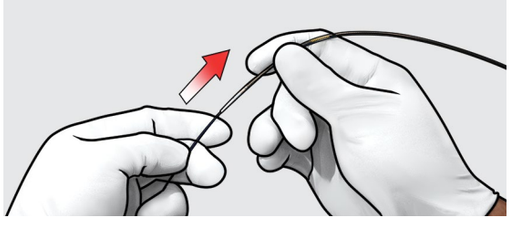
QUICK REFERENCE GUIDE

Overview



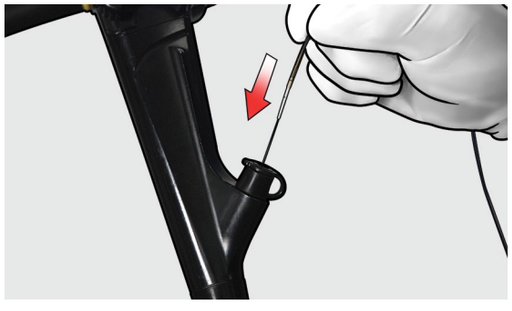
NOTE: For side-by-side stenting, a duodenoscope with a minimum accessory channel diameter of 4.2 mm is required.

Step 1



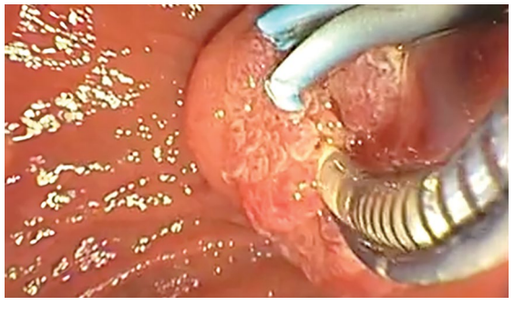
NOTE: For the best results, keep the wire guides wet. Unlock the wire guide, if using a wire guide locking device. Backload the device over the pre-positioned wire guide, ensuring the wire guide exits the wire guide hub.

Step 2a



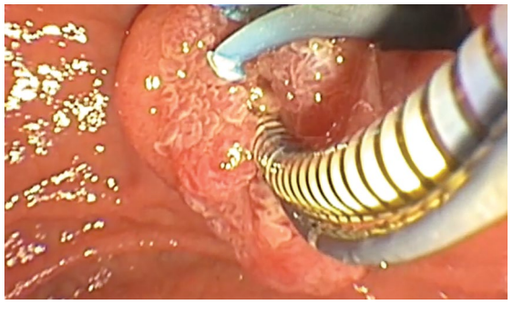
Introduce the device in short increments into the accessory channel of the duodenoscope.

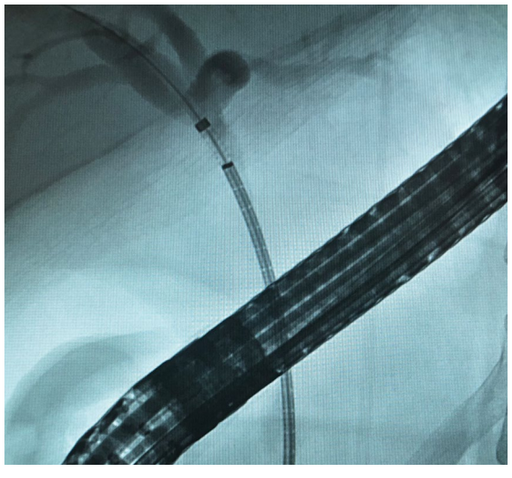
Step 2b



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

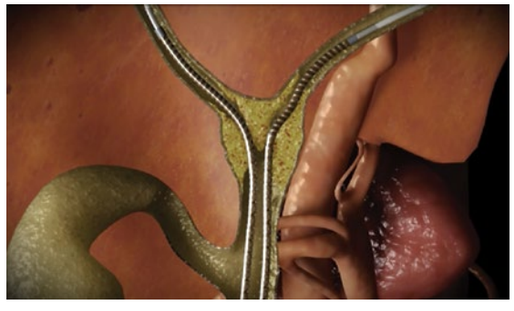
Step 3a





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 position is fluoroscopically visualized 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 3b



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

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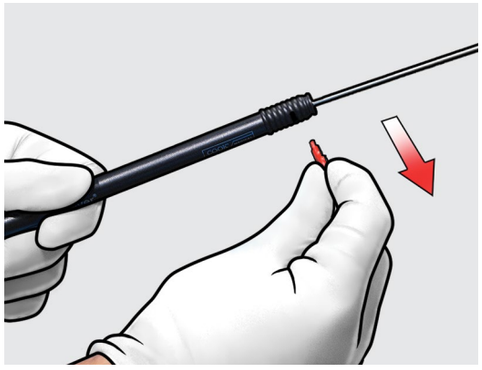
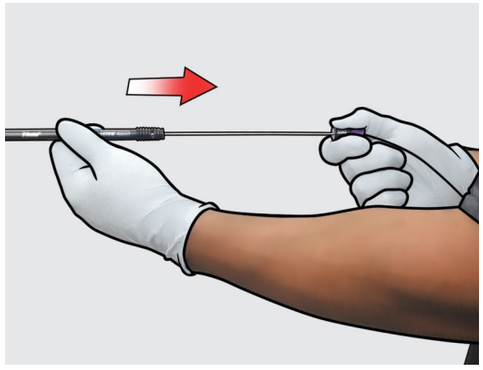
Step 4



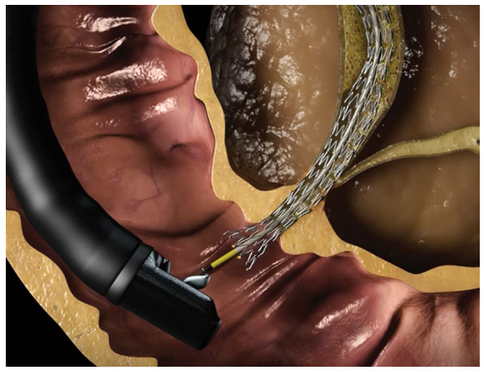
Prior to deploying stent(s), remove the red safety lock(s). **NOTE:** Ensure that the red safety lock(s) is/are not inadvertently removed prior to this step.

Step 5



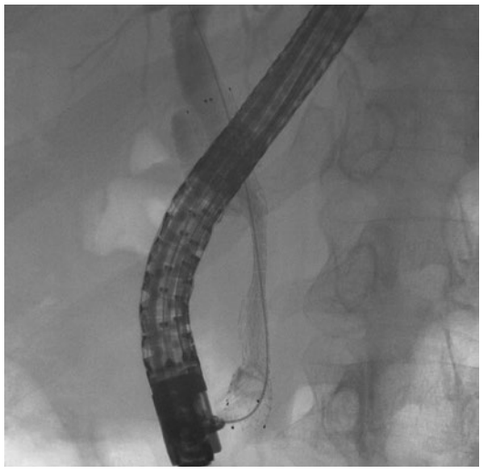
Under fluoroscopic guidance, with the elevator open, begin deployment of the stent(s) by holding the wire guide hub(s) stationary and slowly pulling back on the handle(s). Simultaneously maintain stent(s) position during deployment by withdrawing the delivery system(s) from the duodenoscope.

Step 6



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

Step 7



While maintaining wire guide 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 the stent has expanded sufficiently to allow for the safe removal of the tip.
NOTE: Repeat step 7 for removal of a second delivery system.

Zilver 635® Biliary Stent

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: Contraindications include 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 delivery system through the obstructed area – Very small intrahepatic ducts – Biliary duct strictures of benign etiology – Biliary obstruction preventing cholangiography – Concurrent perforated bile duct – Concurrent bile duct stones – Patients for whom endoscopic procedures are contraindicated – Patients with coagulopathy – Any use other than that specifically outlined in the Intended Use section of this document

WARNINGS: The safety and efficacy of combined side-by-side with overlapping stents has not been established. • The safety and effectiveness of this device for use in the vascular system has not been established. • This stent is **not intended to be removed** and is considered to be a permanent implant. Attempts to remove the stent after placement may cause damage to the surrounding mucosa. • This device is **not** intended to be deployed through the wall of a previously placed or existing metal stent. Doing so could make it difficult or impossible to remove the delivery system. • The stent contains nickel, titanium, and gold, which may cause allergic reaction in individuals with nickel, titanium, or gold sensitivity. • These metal biliary stents are not intended to be repositioned or removed after deployment in the bile duct. In case of accidental deployment or improper placement (immediately following deployment), leave the stent in place and placement of a second stent should be attempted. • Upon removal from package, inspect the product to ensure no damage has occurred. If the package is opened or damaged when received, do not use the device. Visually inspect the device with particular attention to kinks, bends or breaks. If an abnormality is detected that would prohibit proper working condition, do not use the device. Notify Cook for return authorization. • 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. • Do not advance the delivery system up into the bile duct after stent deployment has been initiated. • Do not use the product if there is doubt as to whether the product is sterile. • Sterile if package is unopened or undamaged. • After stent placement, alternative methods of treatment such as chemotherapy and irradiation may increase the risk of: a) stent migration due to tumor shrinkage, b) stent erosion of the tissue, and/or c) mucosal bleeding.

PRECAUTIONS: This device is intended for use by physicians trained and experienced in ERCP techniques and biliary stenting. Standard techniques for the ERCP should be employed. • This device is not compatible with the Cook Medical THSF wire guide. • Refer to the package label for the minimum channel size required for this device. • Prior to stent placement, a complete diagnostic evaluation should be performed to determine the appropriate stent length and diameter. The stent length chosen should allow for additional length on both ends 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. In relation to the lesion site, the area of narrowing furthest away from the papilla should be stented first and the area nearest to the papilla should be stented second. This second stent should provide adequate overlap (at least 1 cm) with the initially placed stent to ensure a bridging of the stricture between the stents. • This stent must be placed under fluoroscopic monitoring. • This stent must only be placed using the delivery system provided. • 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. • If the wire guide or delivery system cannot be advanced through the obstructed area, do not attempt to place the stent. • 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. • Take care not to kink the device during use. • Do not expose the delivery system to organic solvents (e.g., alcohol). • Do not excessively torque the device. • Use of balloon dilation after stent placement has not been evaluated. • Following stent placement, if resistance is met during the withdrawal of the delivery system, carefully remove the delivery system and wire guide as a unit. • **Do not** attempt to reload a deployed or partially deployed stent. • The delivery system cannot be readvanced over the stent to recapture the stent during 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 • liver abscess • 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 • nausea • obstruction of the pancreatic duct • pain • perforation • recurrent obstructive jaundice • stent migration • stent misplacement • stent occlusion • trauma to the biliary tract or duodenum • tumor ingrowth or excessive hyperplastic tissue ingrowth • tumor overgrowth • vomiting.

See Instructions for Use for full product information.

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Please refer to the product's Instructions for Use (IFU) for full prescribing information, warnings, precautions, contraindications, and potential adverse events.

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.

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