More control, less stress.

Evolution® Biliary

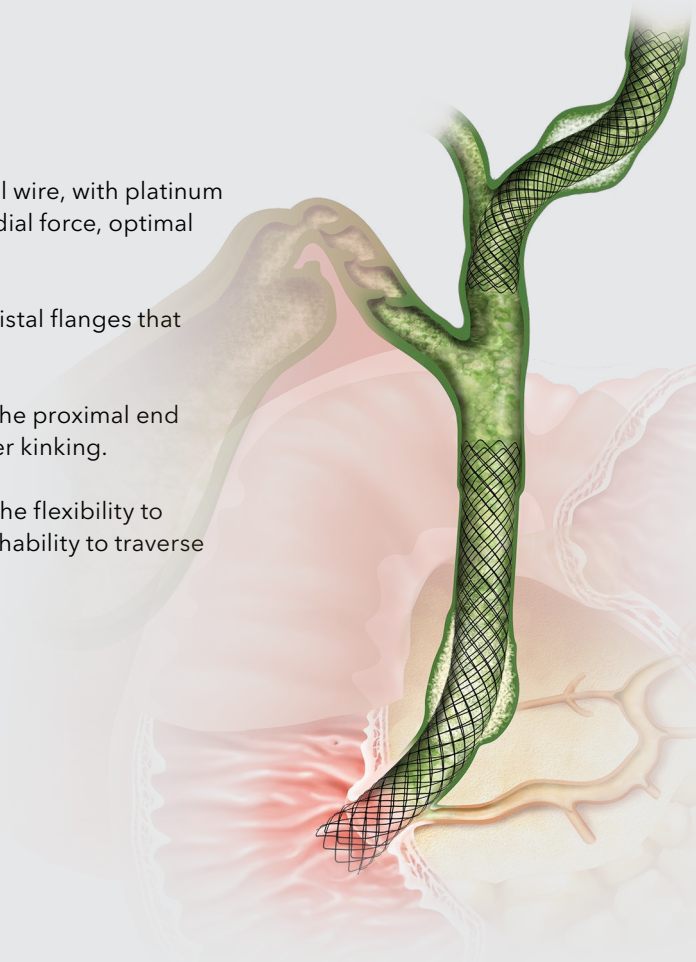
CONTROLLED-RELEASE STENT

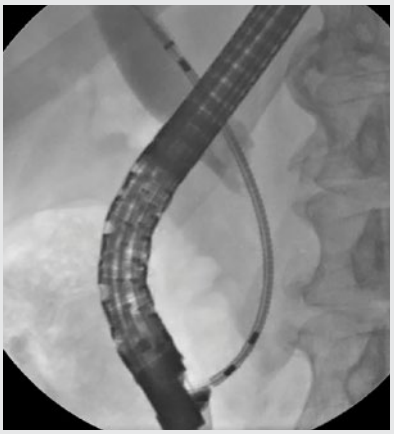
COOK MEDICAL

Evolutionary design

Even when in a completely retroflexed position, you are able to effectively deploy a stent designed for prolonged patency.

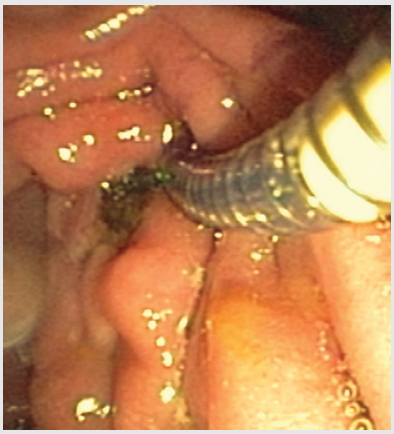
- Evolution stents are woven with a single nitinol wire, with platinum core, which is designed to provide uniform radial force, optimal flexibility, and conformability.
- Every Evolution stent has both proximal and distal flanges that help reduce migration.
- Flexor's coiled-spring reinforcement beyond the proximal end of the stent minimizes the potential for catheter kinking.
- The kink-resistant Flexor technology delivers the flexibility to navigate tortuous anatomy along with the pushability to traverse tight strictures.





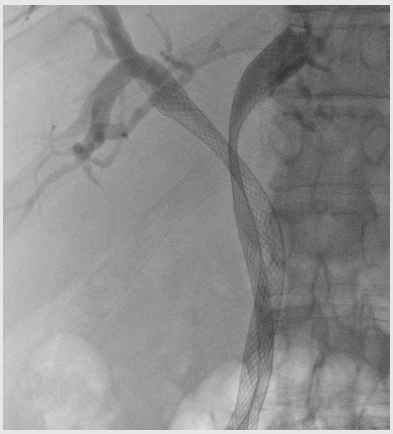
Radiopaque markers before deployment begins

Image courtesy of Prof. Marco Bruno, Erasmus Medical Centre, Rotterdam, the Netherlands.



Endoscopic yellow marker

Image courtesy of Prof. Horst Neuhaus, Evangelisches Krankenhaus, Düsseldorf, Germany.

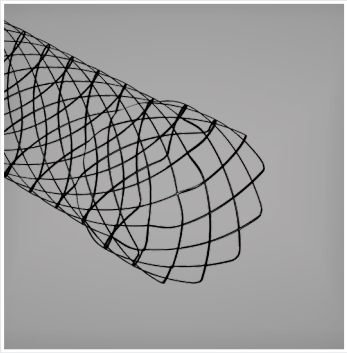


Double stenting immediately after placement

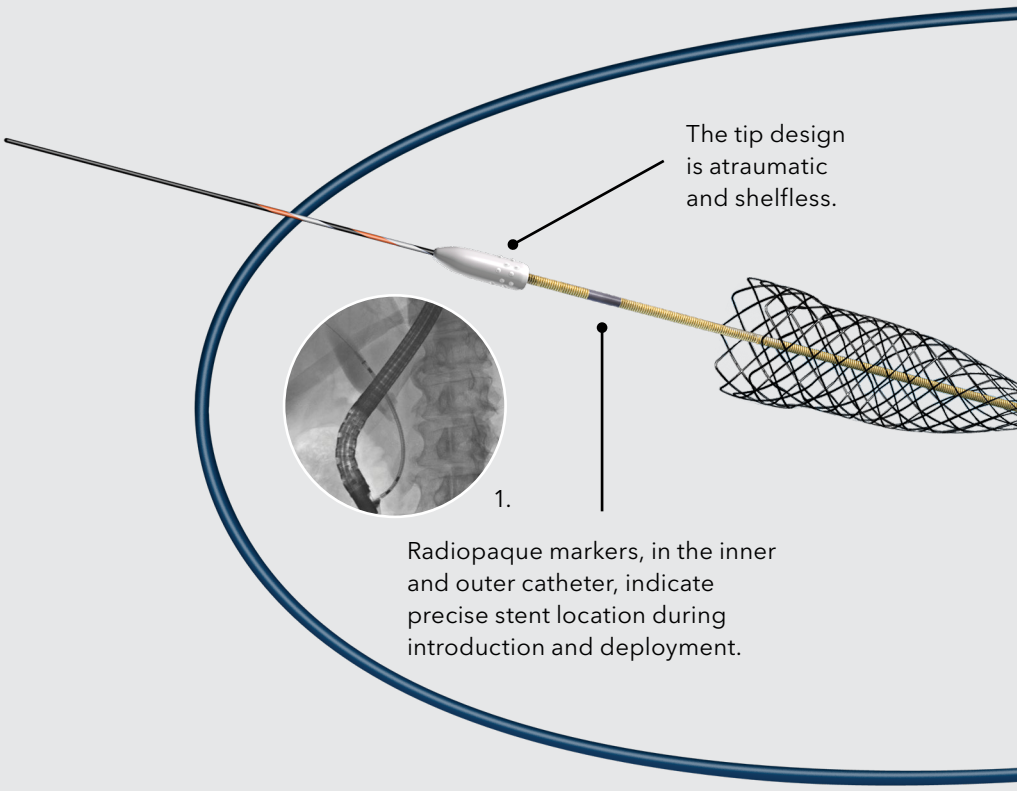
Image courtesy of Prof. Guido Costamagna, Policlinico Universitario Agostino Gemelli, Rome, Italy.

Evolutionary precision

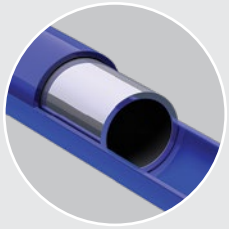
Precision is gaining access to your stenting position and then maintaining that position throughout the deployment process, even in complex and challenging anatomy.

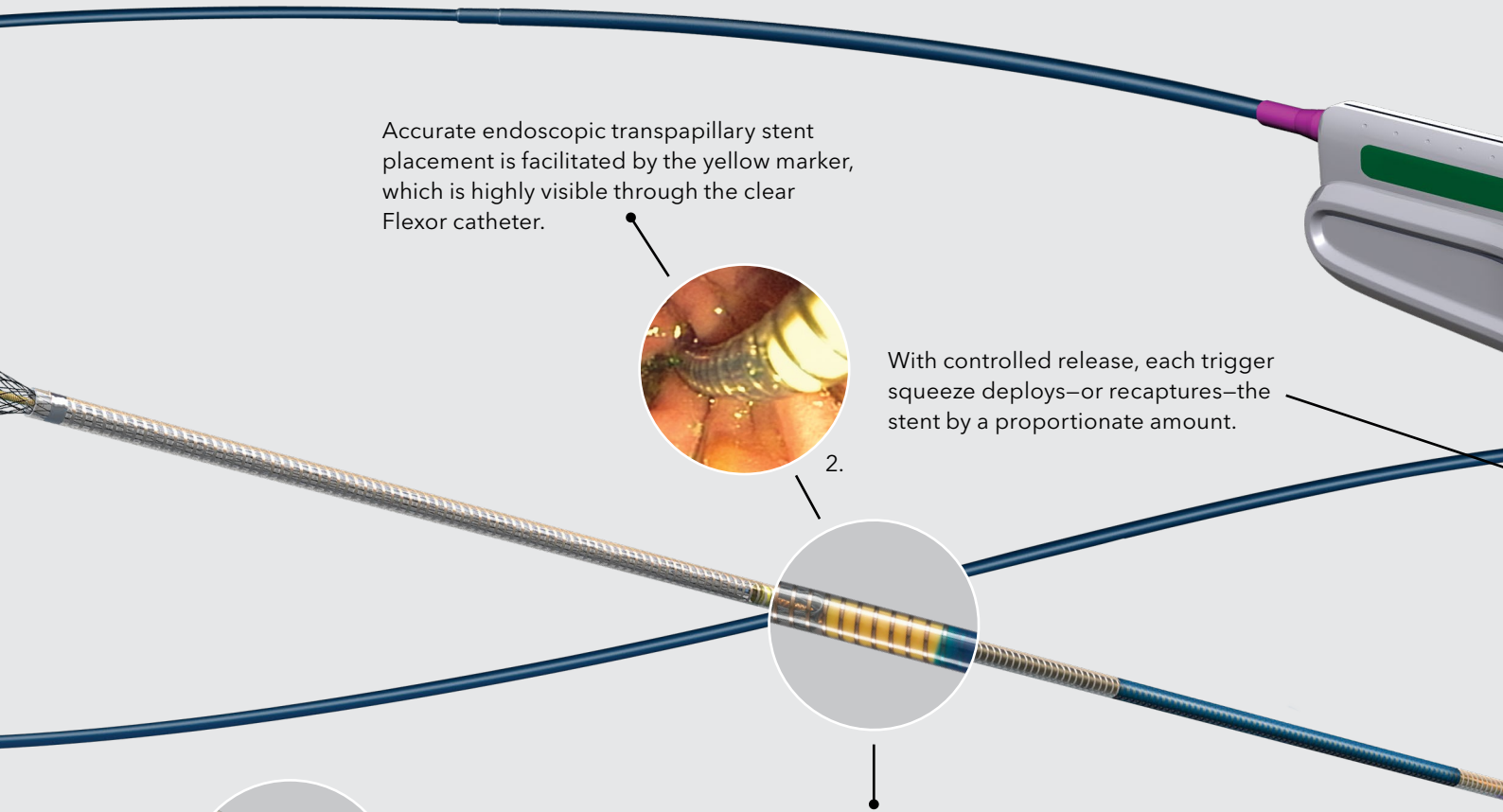


Uncovered



The kink-resistant Flexor® technology delivers flexibility for navigating tortuous anatomy and pushability for traversing tight strictures.

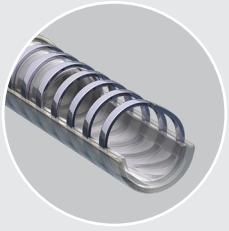




Accurate endoscopic transpapillary stent placement is facilitated by the yellow marker, which is highly visible through the clear Flexor catheter.

With controlled release, each trigger squeeze deploys—or recaptures—the stent by a proportionate amount.

2.

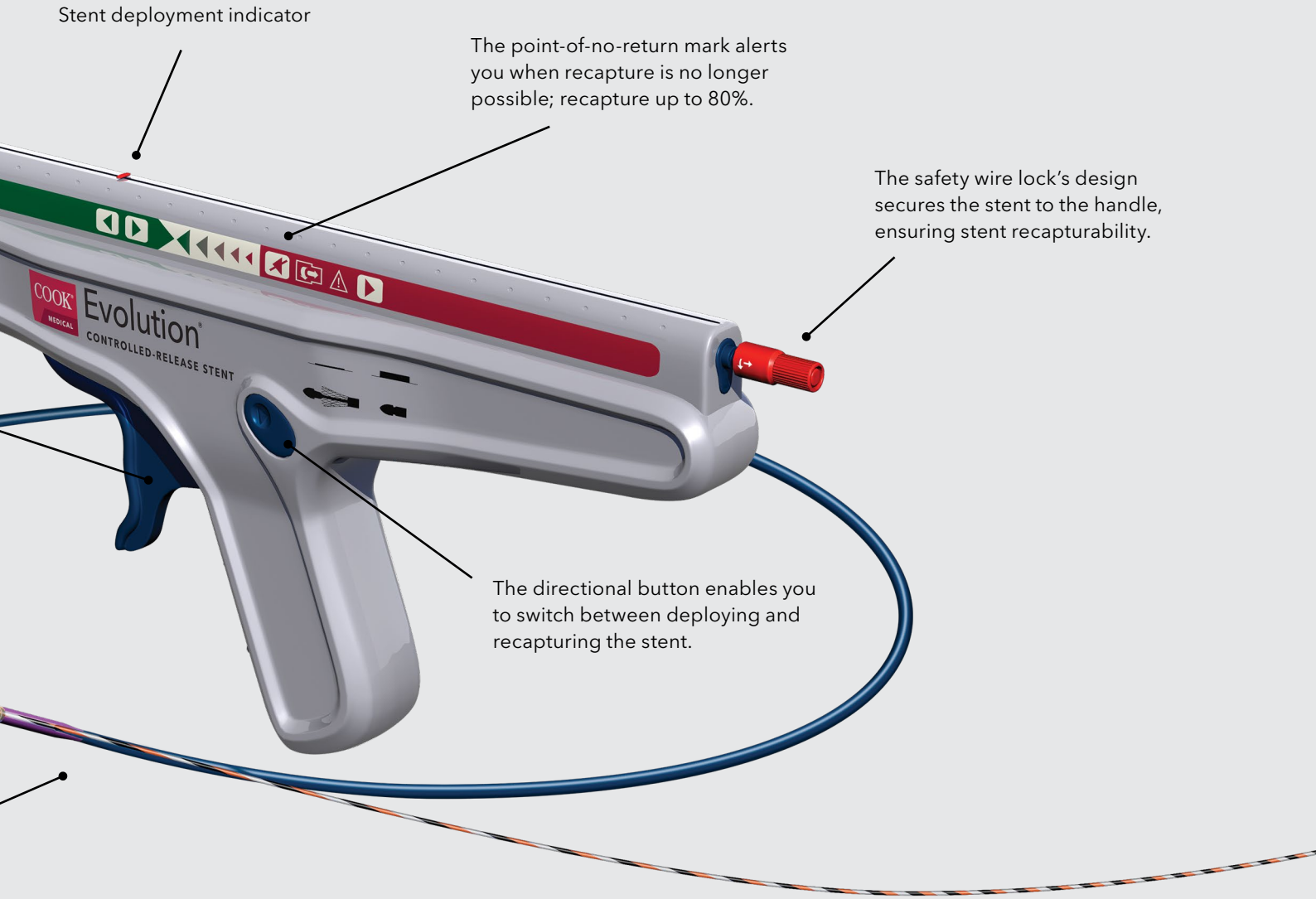


Flexor's coiled-spring reinforcement beyond the proximal end of the stent minimizes the potential for catheter kinking.

Incorporating fusion technology, this system offers the ability to monorail with a long or short wire guide through the zip port.

Evolutionary control

A controlled-release system with the ability to recapture gives you and your assistant the confidence needed to remain in sync throughout the deployment process. The controlled-release mechanism minimizes potential stent jumping, allowing for precise stent placement.



1. Image courtesy of Prof. Marco Bruno, Erasmus Medical Centre, Rotterdam, the Netherlands.
2. Image courtesy of Prof. Horst Neuhaus, Evangelisches Krankenhaus, Düsseldorf, Germany.

Product specifications

This device is used in palliation of malignant neoplasms in the biliary tree. This device is supplied sterile and is disposable. It is intended for single use only.

Order Number	Reference Part Number	Body Diameter mm	Flange Diameter mm	Stent Length cm	Delivery System Fr	Minimum Accessory Channel mm
Uncovered						
G23123	EVO-8-9-4-B	8	9	4	8.5	3.2
G23124	EVO-8-9-6-B	8	9	6	8.5	3.2
G23125	EVO-8-9-8-B	8	9	8	8.5	3.2
G23126	EVO-8-9-10-B	8	9	10	8.5	3.2
G23127	EVO-10-11-4-B	10	11	4	8.5	3.2
G23128	EVO-10-11-6-B	10	11	6	8.5	3.2
G23129	EVO-10-11-8-B	10	11	8	8.5	3.2
G23130	EVO-10-11-10-B	10	11	10	8.5	3.2

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

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Distribution for details.
Please see product risk information in the IFU at cookmedical.com.

MR Conditional

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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