Precision* stenting from the hilum through the papilla.

NOW

Available with 10 cm & 12 cm Lengths

Zilver 635® Biliary

SELF-EXPANDING STENT

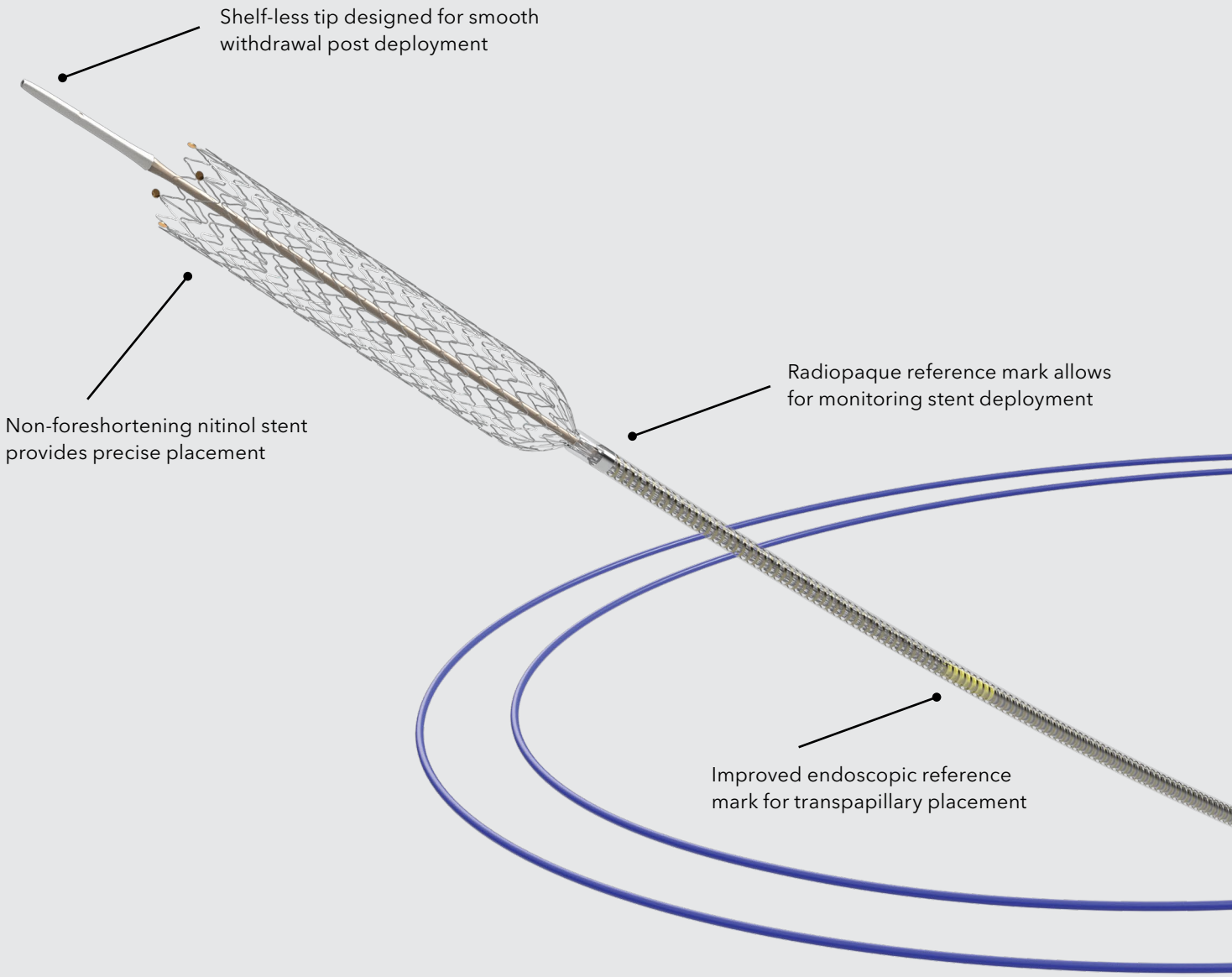
COOK® MEDICAL

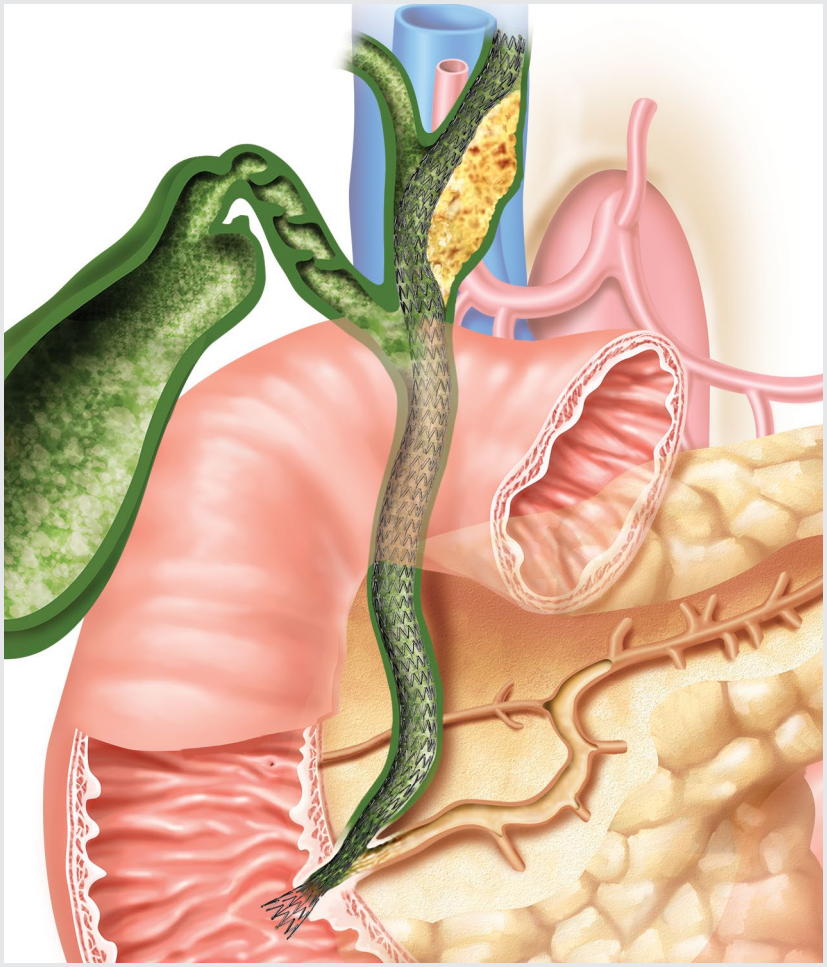
*ZILBS-635 verification testing on file for deployment accuracy.

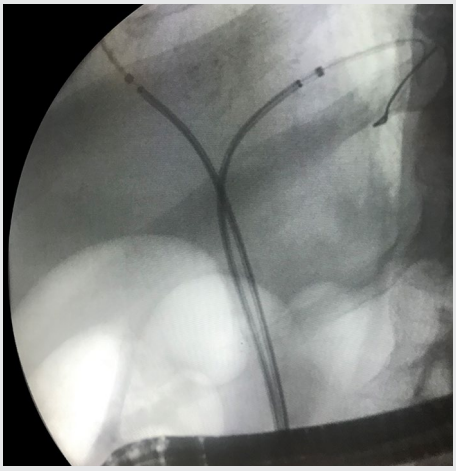
Warning: The safety and effectiveness of this device for use in the vascular system have not been established.

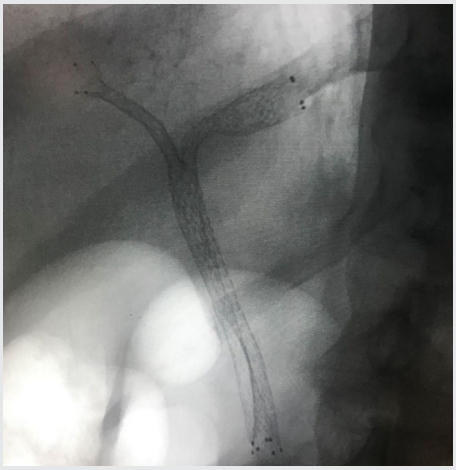
Hilar stenting with a 6 Fr introducer.

Thanks to a slim 6 Fr introducer, you can now deliver all the benefits of the Zilver to the hilar region. The Zilver 635 balances important traits – such as nonforeshortening, radial force, flexibility and patency allowing confidence in stent performance while you focus on providing better results for your patient.









Images courtesy of Dr. Mohammed Barawi
Chief of Gastroenterology Ascension
St. John Hospital, Detroit, MI.

Product Specifications

Order Number	Reference Part Number	Stent Diameter mm	Stent Length cm	Introducer Fr	Introducer Length cm	Wire Guide† Diameter inch
G50616	ZILBS-635-6-4	6	4	6	200	.035
G50619	ZILBS-635-6-6	6	6	6	200	.035
G50622	ZILBS-635-6-8	6	8	6	200	.035
G23811	ZILBS-635-6-10*	6	10	6	200	.035
G23812	ZILBS-635-6-12*	6	12	6	200	.035
G50617	ZILBS-635-8-4	8	4	6	200	.035
G50620	ZILBS-635-8-6	8	6	6	200	.035
G50623	ZILBS-635-8-8	8	8	6	200	.035
G23813	ZILBS-635-8-10*	8	10	6	200	.035
G23814	ZILBS-635-8-12*	8	12	6	200	.035
G50618	ZILBS-635-10-4	10	4	6	200	.035
G50621	ZILBS-635-10-6	10	6	6	200	.035
G50624	ZILBS-635-10-8	10	8	6	200	.035
G23815	ZILBS-635-10-10*	10	10	6	200	.035
G23816	ZILBS-635-10-12*	10	12	6	200	.035

**Check for availability. †Recommend Acrobat® 2 wire guide, sold separately. Minimum accessory channel 2.8 mm.*

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Service for details.

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 effectiveness of this device for use in the vascular system has not been established. The safety and efficacy of combined side-by-side with overlapping stents 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.

PRECAUTIONS: This device is intended for use by physicians trained and experienced in biliary stenting. Standard ERCP techniques for placement of biliary metal stents 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 diagnosic 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. • After stent placement, alternate 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. • 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.

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

See instructions for use for full product information.

AB_IFU0065_REV2

Customer Service

EU Website: cookmedical.eu
EDI: cookmedical.eu/edi
Distributors: +353 61239240, ssc.distributors@cookmedical.com
Austria: +43 179567121, oe.orders@cookmedical.com
Belgium: +32 27001702, be.orders@cookmedical.com
Denmark: +45 38487607, da.orders@cookmedical.com
Finland: +358 972519996, fi.orders@cookmedical.com
France: +33 171230269, fr.orders@cookmedical.com
Germany: +49 6950072804, de.orders@cookmedical.com
Hungary: +36 17779199, hu.orders@cookmedical.com
Iceland: +354 800 7615, IS.orders@cookmedical.com
Ireland: +353 61239252, ie.orders@cookmedical.com
Italy: +39 0269682853, it.orders@cookmedical.com
Netherlands: +31 202013367, nl.orders@cookmedical.com
Norway: +47 23162968, no.orders@cookmedical.com
Spain: +34 912702691, es.orders@cookmedical.com
Sweden: +46 858769468, se.orders@cookmedical.com
Switzerland - French: +41 448009609, fr.orders@cookmedical.com
Switzerland - Italian: +41 448009609, it.orders@cookmedical.com
Switzerland - German: +41 448009609, de.orders@cookmedical.com
United Kingdom: +44 2073654183, uk.orders@cookmedical.com

USA Website: cookmedical.com
EDI: cookmedical.com/edi.do

Americas:
Phone: +1 812.339.2235, 800.457.4500, Fax: 800.554.8335
E-mail: orders@cookmedical.com

Australia:
Phone: +61 734346000, 1800777222, Fax: +61 734346001, 1800077283
E-mail: cau.custserv@cookmedical.com

COOK® MEDICAL

AI, ESC, IR, OHNS, PI, RH, SUR-A4