

Get the flexibility<sup>1</sup> and control that you need for your percutaneous biliary procedures.



## Zilver 635<sup>®</sup> Biliary Stent



# A precise and durable stent, designed for better results for your patients

The **Zilver 635 Biliary Stent** stent balances the most important stent traits: radial force<sup>3</sup>, flexibility<sup>1</sup>, and resistance to shortening<sup>4</sup>. You can rely on this stent for precise delivery and excellent patency rates.<sup>2</sup> Because you can be confident in the stent's performance, you can focus on providing better results for your patient.

The 6.0 Fr 40 cm delivery system is specifically designed for percutaneous biliary procedures. To ensure that you will always have the right device for your patient, Cook Medical also offers a wide variety of accessory products.



## Precision

The **Zilver 635 Biliary Stent** stent resists shortening upon deployment<sup>4</sup>. The four gold markers enhance visibility during fluoroscopy, and the electropolishing results in a smooth and durable stent surface.



## Strength and flexibility

The Z-stent cell design ensures optimal wall apposition while maintaining a strong, equally distributed radial force<sup>3</sup> throughout the stent, and provides sufficient kink-resistance<sup>1</sup> within tortuous anatomy without reducing the diameter of the lumen.



## Reliability

The self-expanding nitinol construction provides the flexibility<sup>1</sup> and outward radial force needed in compressed<sup>3</sup> and nonlinear biliary ducts.

1. Kink radius testing, TS060015/1741

2. Loew BJ, Howell DA, Sanders MK, et al. Comparative performance of uncoated, self-expanding metal biliary stents of different designs in 2 diameters: final results of an international multicenter, randomized, controlled trial. *Gastrointest Endosc.* 2009;70(3):445-453.

3. Radial force testing, TS050009/02350

4. Bench deployment testing, TS040131/TS050097/VAL09-0007

# A flexible and efficient delivery system, designed specifically for biliary procedures

The **Zilver 635 Biliary Stent** and its delivery system are designed to make your biliary drainage procedures efficient and effective.

- Flexor® technology gives the delivery system the flexibility, kink resistance, and pushability<sup>5,1</sup> that are needed in tortuous biliary anatomy.
- The flexible 40 cm long delivery system with Flexor technology and a 6.0 Fr outer diameter is specifically designed for percutaneous biliary procedures.
- A convenient pullback handle and a radiopaque marker allow precise and controlled deployment of the stent for smooth delivery into the target anatomy.

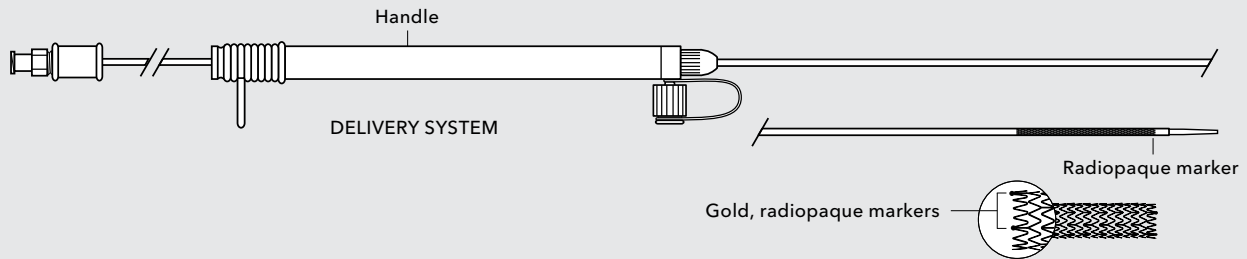
◀ Features a convenient 6.0 Fr 40 cm long Flexor delivery system



Flexor sheath

# Zilver 635® Biliary Stent

Used for palliation of malignant neoplasms in the biliary tree.  
Consult the Instructions for Use for more information.



Order Number	Reference Part Number	Accepts Wire Guide Diameter inch	Stent Diameter mm	Stent Length mm
G31494	ZIB6-40-8.0-40	.035	8	40
G31495	ZIB6-40-8.0-60	.035	8	60
G36011	ZIB6-40-8.0-80	.035	8	80
G32005	ZIB6-40-10.0-40	.035	10	40
G32006	ZIB6-40-10.0-60	.035	10	60
G36013	ZIB6-40-10.0-80	.035	10	80
G53402	ZIB6-40-12.0-40	.035	12	40
G53403	ZIB6-40-12.0-60	.035	12	60
G53404	ZIB6-40-12.0-80	.035	12	80

## Zilver® 518™ and 635™ Biliary Stents

**CAUTION:** U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

**INTENDED USE:** The Zilver 518 and 635 Biliary Stents are intended for palliation of malignant neoplasms in the biliary tree.

**CONTRAINDICATIONS:** Total biliary obstructions and postoperative strictures that cannot be dilated to permit passage of the introducer catheter • Stenting of a perforated duct where leakage from the duct could be exacerbated by placement of a stent • Patients with bleeding disorders • Severe ascites

**WARNINGS:** This stent is **not intended to be removed**. Attempts to remove the stent after placement may cause damage to the surrounding mucosa. This stent is considered to be a permanent implant. • 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. • Possible allergic reactions to nitinol should be considered. • The safety and effectiveness of this device for use in the vascular system have not been established.

**PRECAUTIONS:** Manipulation of the product requires high-resolution fluoroscopic control. • The stent has

not been designed to inhibit tumor ingrowth. Tissue may grow through stents. • Ensure that the red safety lock is not inadvertently removed until final stent release. • Deploy the stent over an extra stiff or ultra stiff wire guide. • Repositioning of the device after deployment is not possible since the introducer catheter cannot be re-advanced over the stent once deployment begins. • This device is designed for single use only. Attempts to reprocess, re-sterilize, and/or reuse may lead to device failure and/or transmission of disease. • Do not attempt to remove the stent from the introducer system before use. • Do not attempt to push the handle away from the hub during deployment. • Do not rotate any part of the system during deployment. • Do not expose the delivery system to organic solvents (e.g., alcohol). Do not use power injection system with the delivery system. • Do not advance the sheath after the stent has been deployed. • Following stent deployment, if resistance is met during the withdrawal of the delivery system, gently re-advance the outer sheath to its pre-deployment position (while continuing to fluoroscopically monitor the stent). Carefully remove the delivery system and wire guide together as a unit. If resistance is still encountered during removal of the delivery system and wire guide as a unit, remove the wire guide, delivery system and access sheath together as a unit.

**See instructions for use for full product information.**

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## Customer Service

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