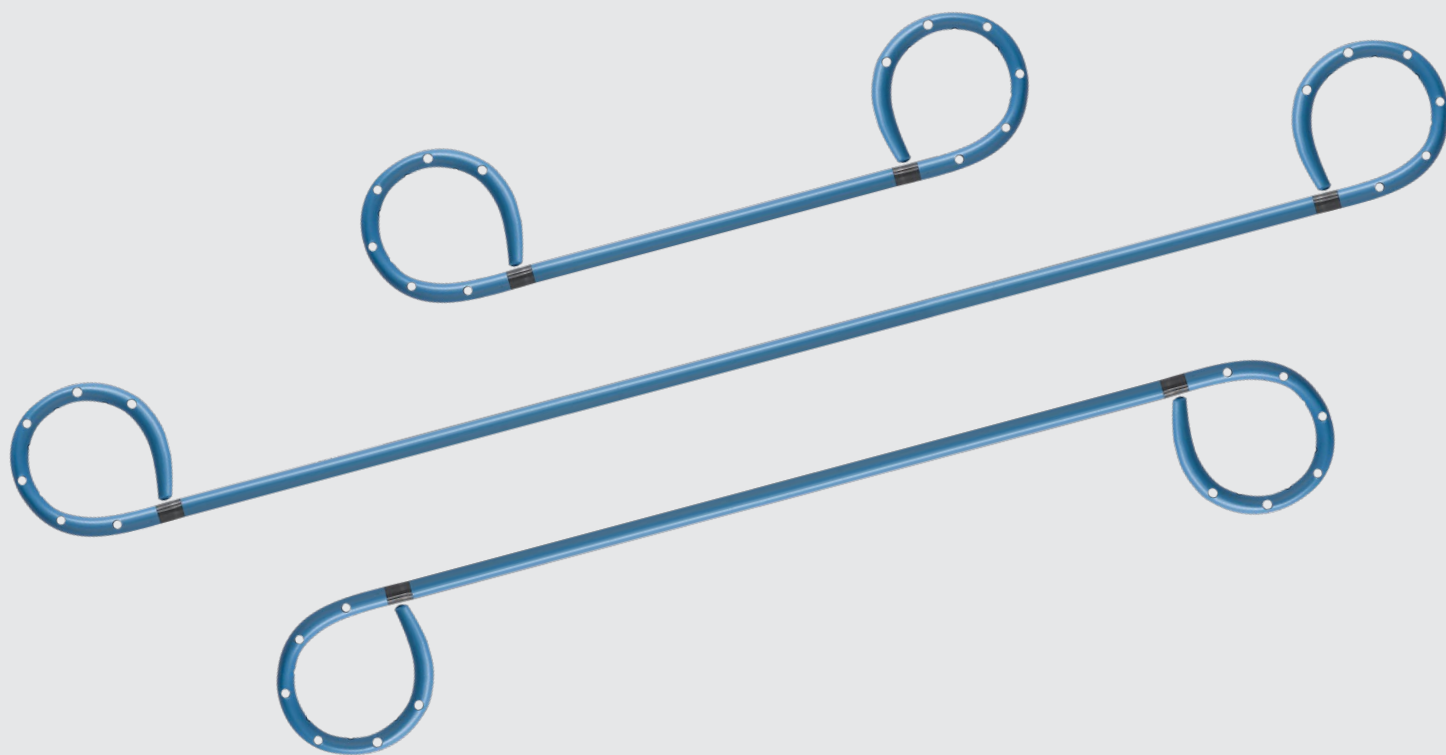
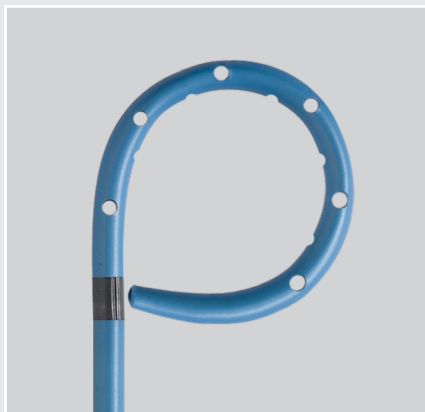


Place biliary stents with  
ease and accuracy.



Compass BDS<sup>®</sup>  
BILIARY STENT



## Compass BDS®

BILIARY STENT

This device is used to drain obstructed biliary ducts.

This product is supplied sterile and is disposable. It is intended for single use only.

- This bidirectional stent offers dual tapered ends to facilitate ease of loading and introduction into the ductal system.
- The double pigtail design features 17 drainage points for each pigtail to optimize drainage.
- Two radiopaque bands provide enhanced fluoroscopic visualization for positioning.

Order Number	Reference Part Number	Fr	Length cm	Minimum Accessory Channel Diameter mm	Wire Guide Diameter inch
G58988	CBBSO-7-5	7	5	3.2	0.035
G58989	CBBSO-7-10	7	10	3.2	0.035
G58990	CBBSO-7-15	7	15	3.2	0.035

Recommended for use with FS-PC-7 or PC-7.

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

### Compass BDS® 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 to drain obstructed biliary ducts.

**INDICATIONS FOR USE:** Endoscopic biliary stent placement for biliary drainage of obstructed ducts that could be caused by common bile duct stones, malignant biliary obstruction, benign or malignant strictures or other obstructed biliary conditions requiring drainage.

**CONTRAINDICATIONS:** Those specific to ERCP. Inability to pass a wire guide and/or stent through the obstructed area.

**WARNINGS:** This single-use device is not designed for re-use. Attempts to reprocess, resterilize, and/or reuse may lead to contamination with biological or chemical agents and/or migration and/or mechanical integrity failure of device. • Visually inspect the integrity of the sterile packaging. Do not use if the sterile packaging is damaged or unintentionally opened before use. • Visually inspect the device 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. • The Compass BDS biliary stent is intended for use up to a maximum of 3 months indwell.

**PRECAUTIONS:** A complete diagnostic evaluation of the patient prior to use to determine the proper stent size should be carried out. • The stent must be placed under fluoroscopic monitoring. • The pigtail straightener is not intended for use in the accessory channel of the endoscope. • Care must be exercised when straightening the pigtail curls in order to avoid kinking or breaking the stent. • Do not use excessive force to advance the stent. • Periodic evaluation of the device is recommended during indwell period. • Select the Cook stent introducer system in the appropriate French size. • Sphincterotomy is not necessary for device placement. • Dislodgement of a placed stent is possible when attempting additional procedures. • Do not use this device for any purpose other than stated intended use. • Store in a dry location, away from temperature extremes. • Use of this device is restricted to a trained healthcare professional. • The product is intended for use by physicians trained and experienced in ERCP techniques.

**POTENTIAL ADVERSE EVENTS:** Those associated with ERCP: allergic reaction to contrast or medication • aspiration • cardiac arrhythmia or arrest • cholangitis • hemorrhage • hypotension • infection • liver abscess • pancreatitis • perforation • respiratory depression or arrest • sepsis. Those associated with biliary stent placement: fever • obstruction of the pancreatic duct • pain/discomfort • stent migration • stent occlusion • trauma to the biliary tract or duodenum.

See Instructions for Use for full product information.

AB\_IFU0135\_REV2

### Customer Service

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