COOK MEDICAL

Compass BDS® Stent
Instructions for Use

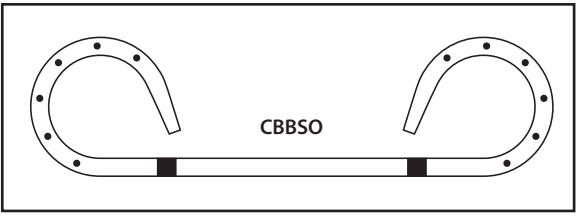

Figure 1: Compass BDS® Stent.

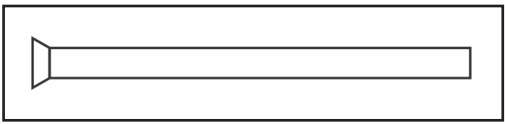

Figure 2: Pigtail straightener.

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).

DEVICE DESCRIPTION

The Compass BDS® Stent (CBBSO) is a biliary stent which includes double pigtails with double radiopaque marker bands and is supplied as stent (with pigtail straightener) only.

Performance Characteristics

The function and key features of these components are described below:

The stents are available in 7 Fr diameter and are offered in lengths of 5, 10, and 15 cm. Compass BDS stents have the following features:

- Atraumatic tip – The ends of the stent are designed to be atraumatic to the anatomy.
- Sideports – Aid drainage.
- Anti-migration features – Aim to help maintain the position of the stent once it is placed by providing mechanical interference with the anatomy.
- Radiopacity – The stent materials are radiopaque to facilitate visibility under fluoroscopy. The stent also contains marker bands to further enhance its fluoroscopic visibility.
- Bidirectional stent ends – The stent ends are bidirectional, and the stent can be loaded on the wire from either end.

Pigtail straightener – This is a tube used to straighten the pigtail to aid in the introduction of the wire guide.

Device Compatibility

Compass BDS Stents are compatible with the following:

- Endoscope with 3.2 mm accessory channel
- 0.035" wire guide
- Endoscopic cap or Fusion wire guide locking device
- Stent retriever or forceps
- Contrast media
- Sterile water or saline
- Standard Luer syringe
- Recommended for use with Cook stent introducers PC-7, PC-7E, and FS-PC-7.

Qualitative and Quantitative Information

The materials for the stent implant are outlined in Table 1.

Table 1: Stent Implant Materials

Product	Qualitative Information Device Material		Quantitative Information Weight (g)
Compass BDS Stent (CBBSO)	Ethylene-vinyl acetate (EVA) copolymer	Stent	Up to 0.93
	Tantalum	Marker bands	Up to 0.051

Patient Population

Adult patients requiring biliary stenting for obstruction. The nature of the underlying pathology is prevalent in varying patients; therefore the devices are indicated for patients with biliary duct obstruction caused by common bile duct stones, malignant biliary obstruction and benign or malignant strictures.

Contact with Body Tissue

This device is tissue contacting in line with intended use.

Operating Principles

The Compass BDS biliary stent operates by providing a lumen through which biliary fluid can drain. The stent has an anti-migration feature which provides mechanical interference with the anatomy to help maintain the position of the stent. The stent is radiopaque to facilitate visibility under fluoroscopy. Sideport(s) on the stent aid drainage by providing additional openings for fluid flow. The double pigtail bidirectional stent tip design allows the stent to be introduced from either side. The biliary stent is placed using a pushing catheter which operates by pushing the stent into place along a pre-positioned wire guide. The pigtail straightener operates by providing a lumen through which the stent can be inserted thus straightening the pigtail to aid in the introduction over the wire guide.

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.

CLINICAL BENEFITS

Drainage of the biliary duct.

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 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.

MRI SAFETY INFORMATION

This symbol means the stent is MR Conditional.

Non-clinical testing has demonstrated that the Compass BDS Stents are MR conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions. Failure to follow these conditions may result in injury to the patient.

- Static magnetic field: 1.5 T or 3 T
- Maximum spatial field gradient: 3000 gauss/cm (30 T/m)
- RF excitation: circularly polarized (CP)
- RF transmit coil type: whole body transmit coil, head RF transmit-receive coil
- Maximum whole body specific absorption rate (SAR): 4.0 W/kg (first level operating mode)
- Limits on scan duration: 4.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
- MR image artifact: the presence of this implant may produce an image artifact of 7 mm.

Note: If information about a specific parameter is not included, there are no conditions associated with that parameter.

For US Patients Only:

It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

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.

HOW SUPPLIED

These devices are supplied ethylene oxide (EO) sterilized in a peel-open pouch.

This device is accompanied by an implant card that should be given to the patient after it has been completed by the healthcare professional.

DEVICE PREPARATION

1. Prior to introducing any devices ensure the working channel of endoscope is lubricated with water or a water-based lubricant.
2. Referring to the device package label, ensure that the endoscope has a channel size greater than or equal to the minimum channel size required to operate the device.
3. Visually inspect the packaging confirming it is unopened and free from damage prior to use.
4. Prior to using the device(s) visually inspect it/them for abnormalities that could result in improper function.

INSTRUCTIONS FOR USE

1. Attach endoscopic cap or wire guide locking device to the endoscope.
2. Use the pigtail straightener to straighten the pigtail.
3. Introduce the stent and the pigtail straightener onto the pre-positioned wire guide until the straightener reaches the second curl.
4. Advance the pushing catheter over the wire guide to advance the pigtail stent into the accessory channel.
5. As the pushing catheter advances the stent completely into the accessory channel, slide the pigtail straightener back over the pushing catheter until it reaches the end of the catheter, keeping it clear of the accessory channel.
6. Advance the pushing catheter in small increments until the stent is in the desired position.
7. Fluoroscopically and endoscopically confirm the desired stent position.

8. After confirming the stent position, gently remove the wire guide from the endoscope while maintaining the position of the stent with the pushing catheter.
9. Gently remove the pushing catheter from the accessory channel.
10. These stents may be removed under standard endoscopic techniques.

DISPOSAL OF DEVICES

This device may be contaminated with potentially infectious substances of human origin and should be disposed in accordance with institutional guidelines.

PATIENT COUNSELLING INFORMATION

Please inform the patient as necessary of the relevant warnings, precautions, contraindications, measures to be taken, and limitations of use that the patient should be aware of.

When available, the EUDAMED website (https://ec.europa.eu/tools/eudamed), along with the BUDI for this product (0827002CIRL202007013010B6), can be used to locate the Summary of Safety and Clinical Performance (SSCP) for this product.

Patient-facing information may be accessed at cookmedical.eu/patient-implant-information.

SERIOUS INCIDENT REPORTING

If any serious incident has occurred in relation to the device this should be reported to Cook Medical and the competent authority of the country where the device was used.

A symbol glossary can be found at cookmedical.com/symbol-glossary

This symbol indicates the minimum accessory channel

This symbol indicates the wire guide size

This symbol is an indication that the device is a medical device

This symbol indicates that the device should not be used if the package (including sterile barrier) has been damaged or opened and to consult the instructions for use

This symbol indicates a single sterile barrier system and identifies the sterile barrier system layer

Rx ONLY

STERILE | EO

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