

Strange Bile Duct Stone Exploration Set

Instructions for Use



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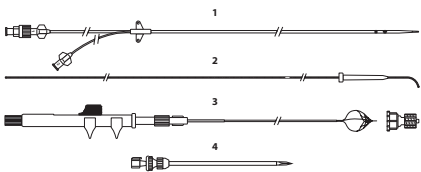


Fig. 1

1. 7.5 French Double Lumen Catheter with Preloaded Inner Catheter
2. Coated Wire Guide
3. NCompass® Nitinol Tipped Stone Extractor with Tuohy-Borst adapter
4. 10.0 French Introducer Catheter with Preloaded Needle Stylet

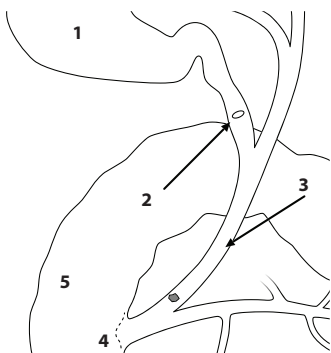


Fig. 2

1. Gall Bladder
2. Cystic Duct (with dissection point, for reference)
3. Common Bile Duct
4. Ampulla
5. Duodenum

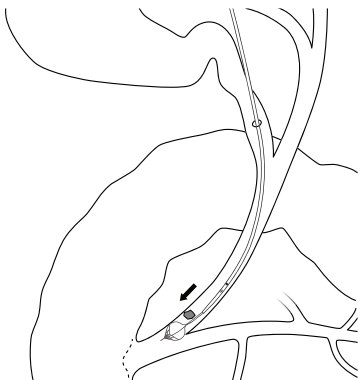


Fig. 3

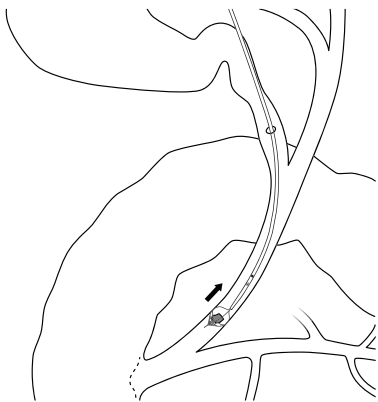


Fig. 4

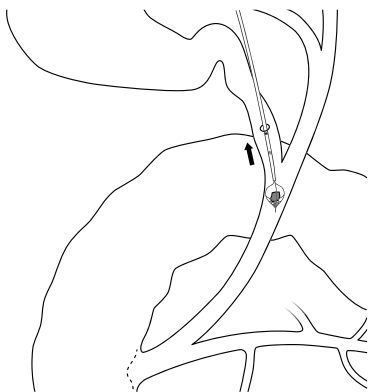


Fig. 5

STRANGE BILE DUCT STONE EXPLORATION SET

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

DEVICE DESCRIPTION

The Strange Bile Duct Stone Exploration Set is packaged and sterilized. The set includes: (Fig. 1)

- 7.5 French, double lumen, 40 cm long radiopaque polyurethane catheter with preloaded inner catheter. Depth markers are located at sideport and 3 cm from the distal end of the catheter.
- 125 cm long, PTFE-coated wire guide
- 115 cm long, NCompass Nitinol Tipped Stone Extractor with Tuohy-Borst adapter
- 10.0 French, 12 cm long introducer catheter with preloaded needle stylet

INTENDED USE

The Strange Bile Duct Stone Exploration Set is intended to be used for cholangiography and bile duct stone retrieval using fluoroscopy. The device is indicated for adults only.

CONTRAINDICATIONS

- Peritonitis
- Severe cholangitis
- Severe acute pancreatitis
- Large bile duct stones which cannot be extracted through the cystic or bile duct, as identified by evaluation of duct diameter and stone diameter at the time of surgery
- Stones greater than 8 mm in diameter should not be removed using the stone extractor basket.
- Previous abdominal operations which prevent safe abdominal access or procession of the procedure
- Inability to advance the catheter through the biliary tree and common bile duct
- Coagulopathy
- Known or suspected perforation of the cystic and/or bile duct

WARNINGS

- Rigidity of the catheter assembly may cause cystic or bile duct perforation during biliary cannulation, especially when acute inflammation is present or deployment past an impacted stone is encountered.
- Wire deployment within the ampulla of Vater and duodenum may entrap mucosa anchoring the catheter assembly *in situ*, potentially injuring mucosa and triggering pancreatitis.
- This device can conduct electrical current. Avoid contact with any electrified instrument.
- The device is designed for the removal of stones and debris no larger than 0.8 cm in diameter.

PRECAUTIONS

- This product is intended for use by physicians trained and experienced in the anatomy of the biliary tree and stone extraction techniques.
- Kinking of the catheter's tip may obstruct advancement of the stone extractor.
- Stone extraction via the cystic or bile duct may lead to stone fragmentation.
- Withdrawal of the stone extractor back into the catheter, in preparation for biliary re-cannulation, may lead to entanglement damaging the wires.
- Pulling on the sheath while advancing or retracting the stone extractor may damage the device, rendering it inoperable.
- If resistance is encountered while attempting to remove a stone or other debris, release the object. Excessive force could damage the device, for example, by making it impossible to open or close the device or by causing the stone extractor to separate.
- Avoid deploying the stone extractor in the ampulla of the distal common bile duct. Mucosa may catch in the stone extractor wires, potentially inducing acute pancreatitis or resulting in long-term ampullary scarring. Early resistance upon stone extractor withdrawal and fluoroscopic inversion of the ampulla and the distal common bile duct are indicators of entanglement.
- The potential effects of phthalates on pregnant/nursing women or children have not been fully characterized and there may be concern for reproductive and developmental effects.

POTENTIAL ADVERSE EVENTS

- Bleeding
- Fragmentation of stones in the bile duct
- Ampullary edema
- Bile duct perforation

- Pancreatitis
- Retained bile duct stones
- Retained stones in the peritoneal cavity
- Stone impaction
- Splitting of cystic duct or bile duct

INSTRUCTIONS FOR USE

Preparation for Use

1. Remove contents from the package in a sterile manner and place on a sterile field.
2. Remove the stone extractor from its outer package and move the thumb tab on the handle to the 'Close' position to close the stone extractor.
3. Examine the contents to ensure that all components are intact and assembled correctly.
4. Flush both lumens of the double lumen catheter with sterile saline.

Access and Cholangiography

1. Initiate standard laparoscopic exposure of biliary anatomy.
2. During dissection of the cystic or bile duct, note the duct size. If accessing via the cystic duct, dissect down closer to the common bile duct to avoid spiral valves. **(Fig. 2)**
3. Identify access point and insert introducer catheter with preloaded needle stylet. Do not insert introducer catheter or needle into the cystic or bile duct anatomy.
4. Remove needle stylet, leaving the introducer catheter in place. Introducer catheter shall remain in peritoneal cavity for duration of procedure.
5. Straighten the wire guide using the straightener. Pass the straightened wire guide through the Check-Flo® valve of the introducer catheter.
6. Under fluoroscopy, ensure wire guide enters the targeted site of cystic or bile duct. If you encounter resistance during the wire guide insertion, do not force the wire guide. Withdrawal of the wire guide through the introducer catheter should be avoided; breakage may result.
7. Advance double lumen catheter (with inner catheter preloaded) over wire guide, through introducer catheter, and into duct. Catheter should be advanced so that at least both depth markers on the distal end of the catheter shaft are inside the duct.
8. Leaving the double lumen catheter in the duct, remove the wire guide and inner catheter.
9. The lumen marked '#2' of the double lumen catheter may be used for the injection of contrast media for visualization under fluoroscopy. **Ensure both depth markers on the distal end of the catheter shaft are inside the duct prior to injection.**
10. Under fluoroscopic imaging, note the duct course into the common bile duct (CBD) (as well as the rest of the biliary tree) and the CBD diameter, coupled with the size, shape, and number of bile duct stones.
11. If there is uncertainty in interpreting images, it may be helpful to wash contrast out with saline and re-run the cholangiogram. Imaging during the washout phase can be helpful, as during the contrast run, to demonstrate details of the stones.

Bile Duct Stone Extraction

1. Once bile duct stones have been confirmed and are considered suitable for extraction, insert stone extractor through the lumen marked '#1' of the double lumen catheter. **NOTE:** The provided Tuohy-Borst adapter may be attached to the proximal end of lumen '#1' of the catheter prior to the insertion of the basket.
2. Under fluoroscopic monitoring, advance the catheter tip just proximal to the first target stone. Advance the extractor sheath through the catheter tip and position the distal end beyond the target stone. **NOTE:** Under fluoroscopic monitoring, the tip of the stone extractor may be visualized.
3. After confirming the stone extractor sheath is positioned alongside or beyond the stone (or debris), open the stone extractor by sliding the thumb tab to the 'OPEN' position. **(Fig. 3) CAUTION:** Avoid deploying the stone extractor in the ampulla of the distal CBD.
4. Maneuver and manipulate the open stone extractor to capture the stone (or debris).
5. Once captured, slowly transition the thumb tab toward the 'CLOSE' position to secure the stone or debris. **(Fig. 4)**
6. Maintain pressure on the thumb tab of the handle to hold the stone (or debris) in place. Slowly retract the stone extractor and double lumen catheter together to facilitate the removal of object from the duct. **NOTE:** The provided Tuohy-Borst adapter may be tightened once the stone is captured to secure the position of the stone extractor during removal. This adapter will not lock the stone extractor on the stone or debris but will secure the position of the stone extractor sheath relative to the double lumen catheter. **NOTE:** Do not use excessive force on the handle. Doing so may result in damage to the device, including but not limited to basket separation or inability to open/close device.
7. Place the stone in a suitable area of the abdominal cavity for its later removal. **NOTE:** Calculi may fragment during removal. Further visual inspection with a small-caliber flexible choledochoscope may be helpful to ensure complete clearance of the stone.

8. After stone removal, patency of CBD can be confirmed by injecting contrast media through the lumen marked '#2' of the catheter and into the duct. **Ensure both depth markers on the distal end of the catheter shaft are inside the duct prior to injection.**
9. For multiple stones, repeat the process (steps 2-7) in sequence, working down toward the ampulla. **CAUTION:** Avoid deploying the extractor in the ampulla of the distal CBD.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Cook sales representative for information on available literature.



This symbol on the label indicates that this device contains phthalates. Specific phthalates contained in the device are identified beside or below the symbol by the following acronyms:

- BBP: Benzyl butyl phthalate
- DBP: Di-n-butyl phthalate
- DEHP: Di(2-ethylhexyl) phthalate
- DIDP: Diisodecyl phthalate
- DINP: Diisononyl phthalate
- DIPP: Diisopentyl phthalate
- DMEP: Di(methoxyethyl) phthalate
- DNOP: Di-n-Octyl phthalate
- DNPP: Di-n-pentyl phthalate

A symbol glossary can be found at <https://cookmedical.com/symbol-glossary>



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