Resolve ConvertX® Biliary Stent System

Instructions for Use

MERITMEDICAL®

Resolve ConvertX®
Biliary Stent System

English

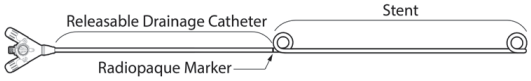
INSTRUCTIONS FOR USE

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
Caution: Complications of biliary stent placement are known and documented. Intended users of this device should be trained in interventional techniques with regards to initial placement of the system. Use of the device should be based on considering the risks and benefits of the specific patient being treated.

1. DEVICE DESCRIPTION

The ConvertX® Biliary Stent System with releasable drainage catheter is used for temporary internal drainage from the biliary duct to the duodenum. The device has two primary components: a double pigtail stent with distal and proximal loops and a releasable drainage catheter. See the figure below.



The hub contains a suture lock for constraining the proximal stent loop in the bile duct when the drainage catheter is attached to the stent. If desired, the physician can remove the drainage catheter, leaving the stent to provide internal drainage from the biliary duct.

The releasable drainage catheter has numeric markings at 5 cm intervals to note position upon initial insertion. A radiopaque marker is located on the proximal part of the stent to aid in accurate placement.

The ConvertX Biliary Stent System comes with stent lengths of 5, 7, 10, and 15 cm, and is 10.3 F in diameter. The system is compatible with standard 0.038" (0.97 mm) guidewires.
The ConvertX Biliary Stent System is intended to treat patients with severe or complete blockages of the biliary system. The system length must be of an appropriate size to span the length of the affected biliary duct.

System Contents
(1) ConvertX Biliary Stent System
(1) Luer Cap
(1) Metal Stiffening Cannula
(1) Plastic Stiffening Cannula
(1) Loop Straightener
System contents are supplied sterile for single use.
Store device in a cool, dry, dark location.

2. INDICATIONS FOR USE

The ConvertX Biliary Stent System with releasable drainage catheter is delivered percutaneously and is intended for internal drainage of the bile ducts, for splinting of the bile ducts during healing, or for providing bile duct patency in a stricture or past a stone while maintaining external access to the stent, as well as providing external drainage. For patients for whom external drainage is not, or no longer desirable, the releasable drainage catheter may be removed, leaving the stent to provide internal drainage from the bile duct to the duodenum.

3. CONTRAINDICATIONS

The ConvertX Biliary Stent System is contraindicated where percutaneous drainage catherization is unacceptable.

4. WARNINGS

Do not use the stent for feeding tube/gastrostomy procedures.
This device is supplied sterile. Do not resterilize or reuse.

5. PRECAUTIONS

- Carefully read all instructions prior to use.
- Do not use if the product or sterile packaging is opened or damaged.
- This device was designed and tested for single patient use only. Do not reuse, reprocess, or resterilize this device. Reuse, reprocessing or resterilization may alter the structural and/or functional integrity of this device which may result in patient injury, infection, illness, or death. Risk of residual contamination and resterilization failure may lead to patient injury, infection, illness, or death.
- Bending or kinking during or prior to placement could damage the integrity of the stent.
- If resistance is encountered during advancement or withdrawal of the stent, STOP. Do not continue without first determining the cause of the resistance and taking remedial action.
- Periodic radiographic, isotopic or endoscopic examinations are recommended to evaluate stent efficiency and to observe for possible complications.
- Release and remove the releasable drainage catheter within the first 30 days of use. If releasable drainage catheter is not going to be removed, the entire system should be removed within the first 30 days of use.
- When long-term use is necessary, the stent should be evaluated for replacement at three-month intervals. This stent is not intended for use as a permanent implant.

Magnetic Resonance Imaging (MRI) Safety Information

MR Conditional

Non-clinical testing has demonstrated the ConvertX Biliary Stent System (complete device, non-detached system) is MR Conditional. A patient with this device can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla, only.
- Maximum spatial field gradient magnetic field of 4000-gauss/cm (40-T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the ConvertX Biliary Stent System (complete device, non-detached system) is expected to produce a maximum temperature rise of 5.3˚C after 15-minutes of continuous scanning (i.e., per pulse sequence).
In non-clinical testing, the image artifact caused by the ConvertX Biliary Stent System (complete device, non-detached system) extends approximately 20-mm from the device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

6. ADVERSE EVENTS

Potential complications associated with indwelling biliary stents and drainage catheters include but are not limited to:

- Extravasation
- Catheter/Stent occlusion
- Catheter/Stent dislodgement
- Hemorrhage/Hematoma
- Infection/Sepsis/Peritonitis
- Pain
- Perforation
- Pneumothorax
- Fistula
- Jaundice
- Pancreatitis

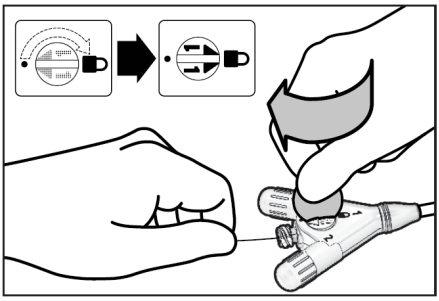
7. OPERATIONAL INSTRUCTIONS

A. PLACEMENT PREREQUISITES

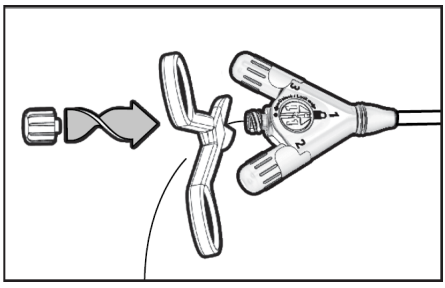
1. The involved biliary system should be visualized via antegrade cholangiography.
2. A stent of proper length should be available. Ideally, the proximal loop should lie within the biliary duct while the distal loop recurves in the duodenum.
3. Fluoroscopy is recommended for more precise control of stent placement. Standard radiography may also be used.

B. STENT PLACEMENT

1. Establish entry into involved biliary duct using a percutaneous access set.
2. Pass the flexible end of guidewire down biliary duct to duodenum.
3. Expand access utilizing increasingly larger sheaths until at least 1F size larger than stent system.
4. Pass appropriate open-end catheter over guidewire to confirm entrance into duodenum and to indicate feasibility of stent placement. Placement of a semi-rigid sheath of appropriate size into the access tract is a useful adjunct at this point.
5. Advance the loop straightener over the proximal loop to aid advancement of the metal stiffening cannula or plastic stiffening cannula.
6. Insert metal stiffening cannula or plastic stiffening cannula into ConvertX catheter while maintaining gentle tension on loop forming suture. Lock stiffening cannula to luer. CAUTION: Inspect distal end of ConvertX system to ensure that the stiffening cannula does not exit the tip of the stent. If the cannula exits the stent do not use the system and replace the device.
7. Remove the loop straightener.
8. Pass the tapered tip of the ConvertX system over guidewire and advance down bile duct.
9. If a change of stiffeners (plastic to metallic or metallic to plastic) is desired during insertion, remove system and exchange stiffeners outside of the body, and then reintroduce system.
10. Using fluoroscopy or ultrasound, confirm distal loop to be in duodenum and proximal loop within biliary duct. Remove guidewire and stiffening cannula while stabilizing ConvertX system.
11. Gently pull suture to form proximal loop. Turn stopcock 180° from the unlocked to locked position following the directional arrows to lock suture in place. CAUTION: Do not use excessive force to form the proximal loop in order to avoid kinking or damaging device. System can be left in place without forming a full loop. If the hub is twisted or torqued during formation of the proximal loop, be sure to allow catheter to relax or untwist before locking the loop.



12. Trim suture and either attach drainage tube or luer cap to luer.



13. Secure the system in place with a suture at the skin so that it can be easily maintained in place by the patient without changing position of the stent. When securing the system, use padding around the catheter to avoid potential kinks from forming.
14. Note on the patient chart and/or implant card the ConvertX system position using the drainage catheter external markings.

ATTENTION ATTENDING PHYSICIAN:
If you will not follow the patient through course of treatment, it is recommended that IFU or a note directing attending physician to link of electronic IFU (www.brightwatermed.com/ifu) be attached to patient chart.

NOTE:
If you plan to remove releasable drainage catheter at the time of system insertion, turning the stopcock and locking the loop suture in step 11 above is not needed. Instead form the proximal loop, trim the loop suture, and then go to step D.3 below for the steps to remove the drainage catheter.

C. METHOD TO REMOVE ENTIRE SYSTEM

1. CAUTION: Confirm tamper seal for cap #3 (for the stent pull release wire) is not broken. If this tamper seal is broken then follow step 4 below for system removal. Note – if upon learning that the tamper seal was broken and it is desired to deploy the stent follow the standard deployment steps in Section D below.
2. Disconnect drainage tube or cap from drainage port on ConvertX hub. Unlock suture by rotating stopcock 180° following the directional arrows to the unlock position.

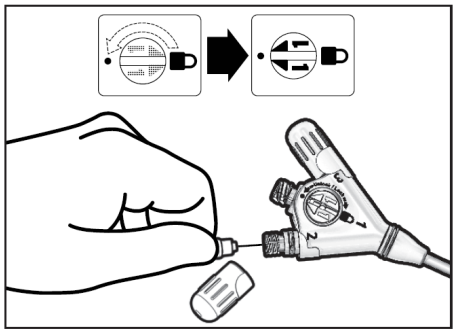
a. If access is to be maintained post removal, follow the below steps:
   i. Prior to inserting a guidewire first remove the ConvertX system's loop suture. Unscrew cap #2 and pull out suture. When removing the loop suture hold the catheter so that it comes straight out of the body without any excessive bends. Suture must be completely removed.
   CAUTION: Do not cut or slice the Releasable Drainage Catheter.
   ii. Insert guidewire (≤0.038") into lumen and advance past distal tip of stent system.

3. Gently withdraw the ConvertX system by pulling from the hub or pulling from the catheter adjacent to the hub.
4. If tamper seal for cap #3 is broken and you believe the stent pull release wire may have been inadvertently pulled and then pushed back into place, follow the below steps to remove the system or disconnect the drainage catheter. If the release wire was pulled then these steps will remove the drainage catheter while leaving the internal stent in place. If the release wire was not pulled then these steps will allow the entire system to be removed.
   a. Disconnect drainage tube or cap from drainage port on ConvertX hub.Unlock suture by rotating stopcock 180° following the directional arrows to the unlock position.
   b. Unscrew cap #2 and pull out suture.When removing the loop suture hold the catheter so that it comes straight out of the body without any excessive bends. Suture must be completely removed.
   c. Withdraw the ConvertX system by pulling from the hub or pulling from the catheter adjacent to the hub.

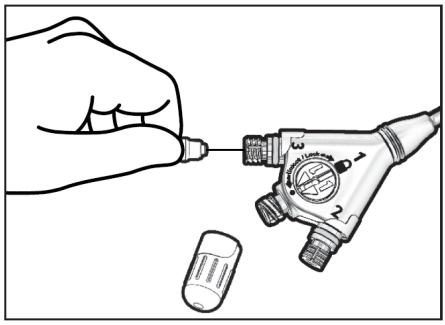
D. METHOD TO DEPLOY STENT / RELEASE DRAINAGE CATHETER

CAUTION: If there is concern that the device may be infected do not release the drainage catheter and deploy the internal stent. Either remove the ConvertX system or replace it with a new device.

1. Verify stent placement.
2. Disconnect drainage tube or cap from drainage port on ConvertX hub. Unlock suture by rotating stopcock 180° following the directional arrows to the unlock position.
3. Unscrew cap #2 and pull out suture. Suture must be completely removed.
   CAUTION: If suture cannot be completely removed, entire system should be removed following system removal instructions.



4. Unscrew cap #3 and pull release wire 3-4 cm or until tension is felt.
   CAUTION: If release wire cannot be pulled a minimum of 2 cm (0.75in.), stent may not have been deployed. Placement of stent or release of catheter should be confirmed before removal.



5. Gently withdraw the drainage catheter out from the percutaneous access site.

E. TROUBLESHOOTING

If any of the previously listed techniques do not work, please contact
Merit Medical Systems, Inc.
1600 West Merit Parkway,
South Jordan, Utah, 84095 U.S.A
1-801-253-1600 U.S.A Customer service 1-800-356-3748

8. SYMBOLS AND MARKINGS

Indicated below are the symbols and markings on the ConvertX packaging label and on the ConvertX Hub.

SYMBOL	DESIGNATION
REF	Catalog Number
LOT	Lot Number
STERILE EO	Sterilized Using Ethylene Oxide
2 STERILIZE	Do not resterilize
	Caution
2	Single Use
	Consult Instructions for Use
	Do not use if package is damaged and consult Instructions for Use.
	Date of Manufacture
	Manufacturer
	Max Guidewire
	Single Sterile Barrier System
	Use By: YYYY-MM-DD
	Temperature Limitation
MD	Medical Device
UDI	Unique Device Identifier
	Break Tamper Seal Per Direction of Physician Only
	Locked
	Unlocked

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1-801-253-1600 U.S.A Customer service
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