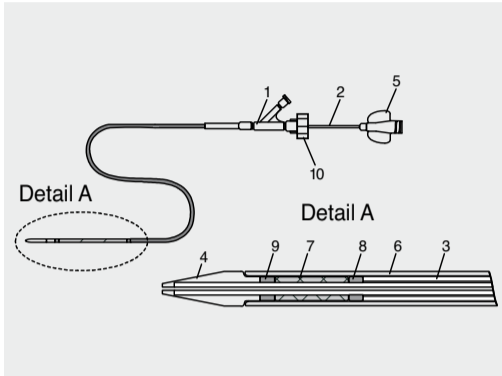


Xpert Biliary Stent

SELF-EXPANDING TRANSHEPATIC BILIARY STENT SYSTEM

INSTRUCTIONS FOR USE



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Xpert Biliary Stent

XPert SELF-EXPANDING TRANSHEPATIC BILIARY STENT SYSTEM

INSTRUCTIONS FOR USE

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

I. DEVICE NAME AND DESCRIPTION

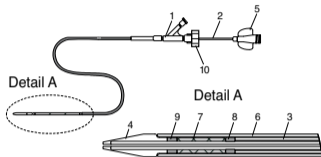
The Xpert Self-Expanding Transhepatic Biliary Stent System consists of a self-expanding stent (Xpert Biliary Stent) integrated into a delivery system, intended for use in the palliation of malignant strictures in the biliary tree.

The Stent

The Xpert Biliary Stent is a self-expanding nitinol stent. The specially treated nitinol material gives the stent properties such as non-crushability. When exposed to body temperature, the stent expands to a preprogrammed diameter. The stent has been specifically designed to show a high degree of flexibility both prior to stent deployment and after implantation in the biliary duct, and to exert radial strength to establish ductal patency.

The Delivery System.

The stent (7) is integrated at the distal end of the delivery system inside the outer tube (6), and rests upon an inner tube through which the guidewire channel runs. To facilitate positioning, two radiopaque markers indicate the stent's proximal (8) and distal (9) end. The inner tube is connected distally to an atraumatic soft tip (4) where the guidewire entry is located. Between the outer and inner tube is a middle tube (3), which ends distally at the proximal end of the mounted stent.



The inner and middle tubes are connected proximally to a metal shaft (2), which runs through the Tuohy Borst adapter (1) and ends proximally with a luer lock (5) where the guidewire exits. The outer tube is connected proximally to the Tuohy Borst adapter. The Tuohy Borst valve is shipped locked. It should be kept locked during handling and introduction of the system to avoid premature deployment of the stent. The Tuohy Borst valve is opened by rotating the proximal valve end (10) in a counter clockwise direction. During stent deployment, the metal shaft should be held in a fixed position while the opened Tuohy Borst valve together with the outer tube are retracted in a proximal direction over the metal shaft to release the stent.

How the System is Supplied

The Xpert Self-Expanding Transhepatic Biliary Stent System is supplied sterile and is intended for single use only.

Storage

The Xpert Self-Expanding Transhepatic Biliary Stent System should be stored in a cool, dry place. Do not expose to organic solvents, ionizing radiation or ultraviolet light.

MRI Compatibility

The implanted stent is MRI safe and does not interfere with, nor is affected by, the operation of a MRI device.

II. INDICATIONS

The Xpert Self-Expanding Transhepatic Biliary Stent System is intended for use in the palliation of malignant strictures in the biliary tree.

III. CONTRAINDICATIONS

All of the customary contraindications to percutaneous transhepatic manipulation of catheters of the same caliber as the Xpert Self-Expanding Transhepatic Biliary Stent System apply, including but not limited to:

- Ascites
- Extensive metastatic disease or tumour spread through the liver
- Intra-arterial chemotherapy

Also including

- Stenting a perforated duct, whereby leakage from the duct could be exacerbated by the self-expandable endoprosthesis and leakage could occur across the mesh of the stent
- Failure to pass the stricture with a guidewire

IV. WARNINGS

- Single use only – do not resterilize. Do not use if inner package is damaged or opened.
- The safety and effectiveness of this device for use in the vascular system have not been established.
- Use prior to the "use by" date. Store in a cool, dry place.
- Once the expansion of the stent has begun, **the stent cannot be retracted into the delivery system or repositioned.**
- The system must always be introduced, moved or withdrawn over a guidewire (0.018").

V. PRECAUTIONS

- This device should only be used by physicians who have a thorough understanding and experience in the clinical and technical aspects of biliary stenting.
- When the system is introduced into the bile duct, it should only be manipulated under high quality fluoroscopy.
- The delivery system is not designed for the use of power injection.
- Do not use with Lipiodol or Ethiodol contrast media.
- Do not advance the Xpert Self-Expanding Transhepatic Biliary Stent System against significant resistance. The cause of resistance should be determined via fluoroscopy and remedial action taken.
- The stent should deploy easily. Do not deploy it if unusual force is required, since this indicates a failed system. Use a new system instead.

VI. POTENTIAL COMPLICATIONS

Complications Relevant to Transhepatic Stent Implantations, e.g.

- Bleeding
- Parenchymal or intraperitoneal hemorrhage
- External biliary fistula
- Perforation, or duodenal perforation
- Cholangitis, possibly leading to sepsis
- Cholecystitis
- Liver abscess
- Biliary peritonitis
- Pleural effusion
- Dislocation
- Death

Complications Related to Concomitant Medication, e.g.

- Drug reactions
- Bleeding from anticoagulation/antiplatelet medication
- Allergic reactions to contrast medium

Complications Related to the Use of the Stent Delivery System, e.g.

- Noncompliance with sterility precautions may lead to infection complications.
- Faulty placement technique may lead to failure in deploying the stent, incorrect implantation of the stent
- Inadequate anchoring due to selection of a too small stent, or intimal trauma if the stent is too large
- Stent migration

VII. PRE-PROCEDURAL PREPARATIONS

Preparation of Patient and Concomitant Medications

Patient preparation and sterile precautions should be the same as for any transhepatic catheter procedure. The medication is decided by the physician, including precautions to reduce clotting during and after the procedure according to latest scientific guidelines and with respect to the individual patient. The intervention should be performed in a procedure room and carried out under X-ray control.

Cholangiography

Cholangiography is performed to map out the strictures and the collateral flow.

Pre-dilatation of Stricture

Perform a bile duct dilatation leaving the guidewire in place across the stricture. Check the duct and stricture dimensions carefully after dilatation in order to choose the correct stent size.

VIII. SELECTION AND PREPARATION OF DEVICE AND COMPATIBILITY WITH ACCESSORIES

Selection of Stent Size

The stent diameter should be approximately 1mm larger than the diameter of the dilated bile duct. The stent length should cover the stricture completely. Should more than one stent be required to cover the stricture, place the distal stent first, followed by the proximal stent(s). Ensure that stents overlap slightly to avoid any gaps.

Preparation of Stent Delivery System

Remove the system from the package. Ensure that the sterile barrier (steri-pouch) is not broken or damaged.

Warning: If broken or damaged – do not use the system.

Inspect the system visually for damages that could influence performance. Inspect that the stent is fully contained within the outer tube. Do not use if the stent is partially deployed or a gap between outer tube and catheter tip is over 2 mm. Make sure that the Tuohy Borst valve is locked by rotating in a clockwise direction. The complete system should be flushed at the Tuohy Borst adapter and the proximal luer lock with saline solution before use.

- Attach a syringe filled with saline solution to the lateral branch of the y-connector and apply positive pressure. Ensure that the Tuohy Borst valve is locked and continue to flush until the saline solution drips from the distal part of the outer tube.
- Flush the central guidewire lumen at the proximal luer lock.

IX. STENT IMPLANTATION PROCEDURE

Introduction of the System

After the initial ductal dilatation procedure, introduce the system through the introducer over a 0.018" guidewire that has been left positioned through the stricture site.

Warning: The system must always be introduced, moved or withdrawn over a guidewire.

Advance the system under fluoroscopic guidance and position the stent with the help of the radiopaque markers at the stricture.

Caution: Do not advance the Xpert Self-Expanding Transhepatic Biliary Stent System against significant resistance. The cause of resistance should be determined via fluoroscopy and remedial action taken. Withdraw the system and use a new one.

Deployment of the Stent

Ensure correct stent position prior to stent deployment, and unlock the Tuohy Borst valve. Hold the metal shaft in a fixed position and retract the outer tube by **slowly** pulling the Tuohy Borst valve over the metal shaft towards the proximal end.

Note: During deployment, the proximal metal shaft should be kept in a **fixed position** as the stent is released by retracting the outer sheath. **Also observe and keep the proximal stent marker in a fixed position for optimal stent placement.**

Caution: Do not push the metal shaft, as this could cause misalignment of the stent and possible ductal damage.

Warning: Once expansion has begun, the stent **cannot be retracted into the delivery system or repositioned.**

Caution: The stent should deploy easily. Do not deploy if unusual force is required, since this indicates a failed system. Use a new system instead.

Deployment is complete when the Tuohy Borst adapter meets the proximal luer lock.

X. POST STENT IMPLANTATION

Withdrawal and Disassembly Procedure

After full deployment of the stent, withdraw the delivery system carefully, leaving the guidewire in place. If the tip of the delivery device catches the distal stent filaments, perform gentle movements in order to free it. Perform routine post-procedural cholangiography.

Further Dilatation of Stented Segments

If the stent is not completely expanded throughout the stricture, post-dilatation inside the stent can be performed.

Warning: Never expand the stent using a balloon that is larger in diameter than the unconstrained diameter of the stent.

XI. PRODUCT INFORMATION DISCLOSURE

Abbott Vascular has exercised reasonable care in the manufacture of this device. Abbott Vascular excludes all warranties, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness, since handling and storage of this device as well as factors relating to the patient, the diagnosis, treatment, surgical procedures, and other matters beyond Abbott Vascular's control directly affect this device and the results obtained from its use. Abbott Vascular shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this device. Abbott Vascular neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.