

Xceed[®]RELEASED

Biliary Stent System

Xceed[®] Nitinol Self-Expanding Transhepatic Biliary Stent System

Instructions for Use

Rx ONLY

Device Description

The Xceed Nitinol Self-Expanding Transhepatic Biliary Stent System is comprised of a delivery system and a self-expanding stent. The delivery system is an over the wire (OTW) system designed to deliver the self-expanding stent to the biliary tree. The self-expanding stent is cut from Nitinol tube into a flexible tubular prosthesis. Upon deployment of the stent into the biliary duct via the delivery system, the stent should appose the duct wall and apply an outward pressure to establish patency. Tantalum radiopaque markers may be located on the ends of the stent. Please refer to the pouch or box label to determine if the stent in use features markers.

The 6F max OD profile delivery system (see **Figure 1** and **Detail A**) is comprised of an **outer sheath** and inner system assembly. The outer sheath is connected to the **handle** via the **nose**. A **flush valve** is installed in

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the nose to facilitate flushing of the space between the outer sheath and inner assembly. The distal 30cm of the outer sheath is coated with hydrophilic coating. The **FREESTYLE™ technology stabilizer** is installed over the connection between the handle and outer sheath to facilitate transition between the two components.

The inner system assembly (see **Detail A**) consists of a **catheter tip** installed over a 0.035" guide wire compatible **inner core**. The inner core extends the entire length of the delivery system, providing a guide wire lumen, and is connected to the **proximal luer**. The inner system assembly also contains an I-BEAM® (see detail A) to support the stent during deployment. I-BEAM originates inside the handle and runs through the sheath up to the proximal end of the stent. The proximal luer facilitates flushing of the guide wire lumen. The **stent** is constrained by the outer sheath between the distal and proximal markerbands of the delivery system.

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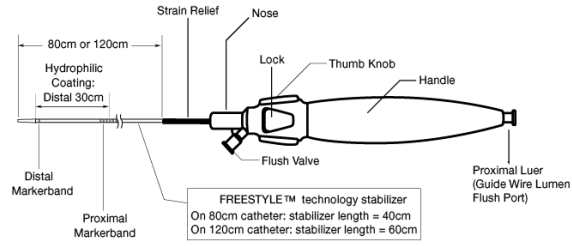
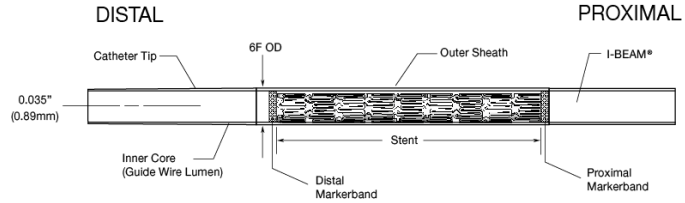


Figure 1: Delivery System Overview



Detail A: Distal View of Delivery Catheter

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Indications for Use

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

Contraindications

Contraindications associated with the use of transhepatic biliary endoprosthesis include:

- Stenting of a perforated duct where leakage from the duct could be enhanced by the prosthesis
- Bleeding disorders
- Severe ascites
- Active infections

Warnings

- The safety and effectiveness of this device for use in the vascular system have not been established.
- The device is provided **STERILE** for single use only and must be used by the “use before date” printed on the package. Do not resterilize and/or reuse this device.
- Carefully inspect the sterile package and device prior to use. **DO NOT** use if either has been damaged or compromised.
- The stent is not designed for capture or repositioning after deployment.
- **DO NOT** attempt to reconstrain the stent at any time during deployment.
- Persons allergic to nickel titanium may suffer an allergic reaction to this implant.
- Do not use with Ethiodol[®] or lipiodol contrast media.

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- Stenting across a major bile duct may compromise future procedures.
 - Do not expose the delivery system to organic solvents (e.g., alcohol).

Precautions

- Store in a cool, dry place.
- Should unusual resistance be felt **at any time** during the procedure, the introducer sheath/guiding catheter and stent system **should be carefully withdrawn as a single unit** (applying excessive force to the stent delivery system can potentially result in loss or damage to the stent and delivery system components).
- If unusual resistance is encountered when attempting to deploy the stent, rotate the thumb knob counterclockwise back to its original position, and relock. Carefully withdraw the stent system as a single unit and discard.
- Special care must be taken not to handle or in any way disrupt the stent on the delivery system. This is most important during delivery system removal from packaging, placement over the guide wire, and advancement through the introducer.
- This device is intended for use by physicians familiar with the complications, side effects, and hazards associated with biliary stent placement.
- The Xceed Nitinol Self-Expanding Transhepatic Biliary Stent System is intended to perform as a system. Individual system parts should not be removed for use in conjunction with other devices (e.g. dilatation catheters stents, etc.).

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- The usage of other stents in conjunction with the Xceed Biliary Stent System is not recommended. When multiple stents are required, and the user elects to use an alternative stent, stent materials should be of similar composition. Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the Xceed Nitinol Self-Expanding Transhepatic Biliary Stent System, for their intended uses, contraindications, and potential complications.
 - The delivery system is not designed for use with powered injection systems.

Potential Complications

Potential complications associated with the use of a biliary endoprosthesis may include, but are not limited to:

- Sepsis/infection
- Bile duct occlusion/obstruction
- Tumor overgrowth
- Bile duct perforation
- Hemobilia
- Abscess
- Cholangitis
- Peritonitis
- Pancreatitis
- Parenchymal hemorrhage
- Stent migration.

1. **Perform a percutaneous cholangiogram** using standard technique.
2. Under fluoroscopy, **carefully evaluate and mark the entire target region.**
3. **Select the appropriate stent size** by measuring the length of the target stricture and the reference diameter of the bile duct.

A suitable stent length should allow for coverage proximal and distal to the tumor in order to minimize the effects of further tumor growth.

The reference diameter of the bile duct should be measured both proximal and distal to the stricture. Select the appropriate stent using the table below (**Table 1**):

Table 1. Xceed Biliary Stent Size Range

Target Duct Lumen Diameter	Stent Unconstrained Diameter	Average % Foreshortening*
3.5 – 4.5mm	5mm	2.3%
4.5 – 5.0mm	6mm	3.0%
5.0 – 6.0mm	7mm	4.0%
6.0 – 7.0mm	8mm	4.7%
8.0 – 9.0mm	10mm	5.0%

* Percent foreshortening results are based upon average values obtained during actual bench testing. Data on file with Abbott Vascular.

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4. **Stent Delivery System Preparation:**

- a. Open the outer box and remove the pouch containing the stent and delivery system.
- b. Inspect the pouch for evidence of damage or breaks in the sterile barrier.

Caution: DO NOT USE device if the sterile barrier appears to be compromised.

- c. Carefully peel open the pouch, and extract the tray. Carefully peel back the tray seal.
- d. Gently remove the device from the tray. Thoroughly inspect the device for any damage.

Caution: DO NOT USE if device appears damaged.

- e. Inspect the lock and ensure that it is fully engaged with the nose of the handle. If it is unlocked, rotate the thumb knob counterclockwise and line up the grey lock with the open slot on the nose. Reengage the lock by pushing it distally.
- f. After reengaging the lock, inspect the distal end of the device for a deployed stent.

Caution: DO NOT USE if the stent appears deployed.

- g. Attach either a 10cc, 5cc or 3cc syringe filled with saline to the flush valve and apply positive pressure until saline trickles from between the outer sheath and catheter tip.

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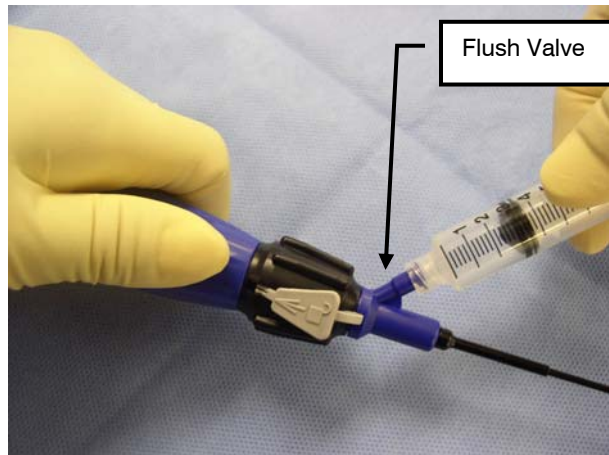


Figure 2: Syringe and distal flush valve

- h. While fixing the proximal luer with left hand, attach either a 10cc, 5cc, or 3cc syringe filled with saline to the proximal luer (guide wire lumen flush port) and apply positive pressure until saline trickles out from the guide wire lumen. (Refer to **Figure 3**)
- i. Hydrate the hydrophilic coating by gently wiping down the delivery catheter with sterile water or saline solution.

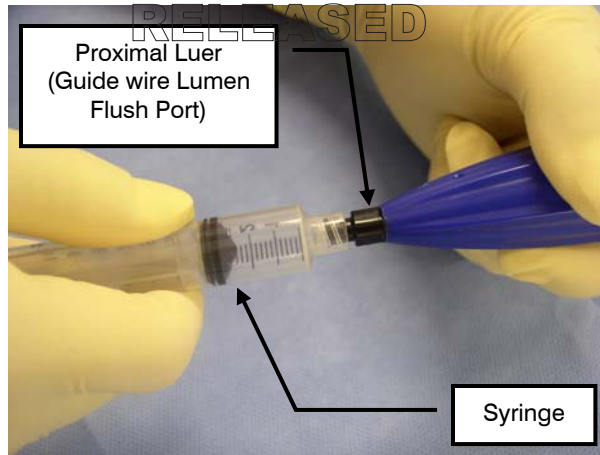


Figure 3: Syringe and proximal flush port

5. Stricture Treatment:

- a. Confirm access site introducer sheath size of 6F or larger.

Caution: To protect both the liver tract and the puncture site, always use an introducer sheath for an implant procedure.

- b. Insert a 0.035" guide wire of appropriate length through the introducer sheath and across the stricture to be stented.
- c. Predilation of malignant strictures is not generally performed, however, a balloon dilation catheter may be used at the discretion of the physician. Following dilation, remove the balloon dilation catheter while maintaining guide wire access across the target stricture.

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Caution: Do not expand the balloon dilation catheter to the point that bleeding or dissection complications could occur.

- d. Load the stent delivery system onto the back end of the guide wire and through the introducer sheath.

Caution: If resistance is encountered during guide wire loading or delivery system introduction, the system should be discarded and another system used.

- e. Advance the stent delivery system until the radiopaque inner assembly markerbands are optimally positioned relative to the target stricture.
- f. Prior to stent deployment, ensure that the FREESTYLE™ technology stabilizer is inserted at least 2cm through the introducer.

Note: Ensure there is no slack in the delivery system prior to deployment.

- g. Unlock the delivery system by pulling back the safety lock. (Refer to **Figure 4**)

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Figure 4: Safety Lock

- h. Deploy the stent by rotating the thumb knob clockwise with the thumb and index finger while holding the handle in a fixed position. (Refer to **Figure 5**)

Caution: If unusual resistance is encountered when attempting to deploy the stent, rotate the thumb knob counterclockwise back to its original position, and relock. Carefully withdraw the stent system as a single unit and discard.

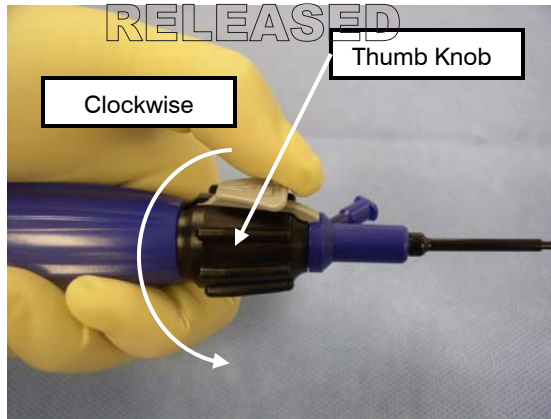


Figure 5: Thumb Knob

- i. Stent deployment is complete when the thumb knob can no longer be turned, and the stent is apposed against the biliary duct wall. Verify via fluoroscopy that the stent is fully deployed.

Note: When more than one stent is required, the more distal stent should be placed first.

- j. Under fluoroscopic guidance, withdraw the entire delivery system over the guide wire as one unit until it is completely removed from the patient.
- k. Post deployment dilation with a balloon dilation catheter may be performed at the discretion of the physician. The inflation diameter of the balloon dilation catheter should approximate the diameter of the reference biliary duct and should not be greater than the diameter of the unconstrained stent.

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- l. Remove the guide wire and sheath from the patient.
 - m. Close the access site, as appropriate.
 - n. Discard the delivery system, guide wire, and sheath.

Note: The appropriate drug regimen for each patient should be determined by physician experience and discretion.

MRI Compatibility

The Xceed Nitinol Self-Expanding Transhepatic Biliary Stent is MRI safe and does not interfere with, and is not affected by, the operation of an MRI device.¹

How Supplied

The Xceed Nitinol Self-Expanding Transhepatic Biliary Stent is supplied sterile (by ethylene oxide gas) and is intended for SINGLE USE ONLY. Do not resterilize and/or reuse this device. Store in a cool, dry place. The device and immediate product packaging are latex free.

Packaged one (1) system per box. Each system contains one (1) Nitinol Self-Expanding Stent with delivery system.

¹ "MRI Imaging Artifacts, Ferromagnetism, and Magnetic Torque of Intravascular Filters, Stents, and Coils," Radiology 1988 166:657-664.

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Product Information Disclosure

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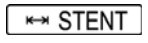
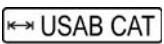

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Graphical Symbols for Medical Device Labeling

	Batch code
	Date of Manufacture
	Use by
	Catalogue number
	Contents
	Number of units
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution, refer to accompanying documents.
	Sterilized using ethylene oxide.
	Do Not Resterilize
	Do Not Reuse
	Non-Pyrogenic
	Latex Free
	Do not use product if packaging or sterile barrier has been previously opened or damaged.

	Store in a cool location (room temperature).
	Keep dry
	Manufactured by
	Distributed by
	Recommended Introducer
	Recommended Guiding Catheter
	Recommended Guide Wire
	Inner Diameter
	Nominal Stent Diameter
	Nominal Stent Length
	Usable Catheter Length
	Over The Wire

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This product and its use are protected under
the following patents:

5,421,955	5,514,154	5,569,295
5,603,721	5,649,952	5,725,572
5,728,158	5,759,192	5,780,807
5,916,234	6,056,776	6,066,167
6,131,266	6,325,824	6,369,355
6,468,302	6,485,511	6,568,235
6,908,479	7,128,756	

Other U.S. and foreign patents pending.

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