

---

## **Dynalink® .018 and .035 Biliary Self-Expanding Stent Systems**

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

- 1.0 DEVICE DESCRIPTION
- 2.0 HOW SUPPLIED
- 3.0 INDICATIONS
- 4.0 CONTRAINDICATIONS
- 5.0 WARNINGS
- 6.0 PRECAUTIONS
- 7.0 ADVERSE EVENTS
- 8.0 CLINICIAN USE INFORMATION
- 9.0 PATENTS

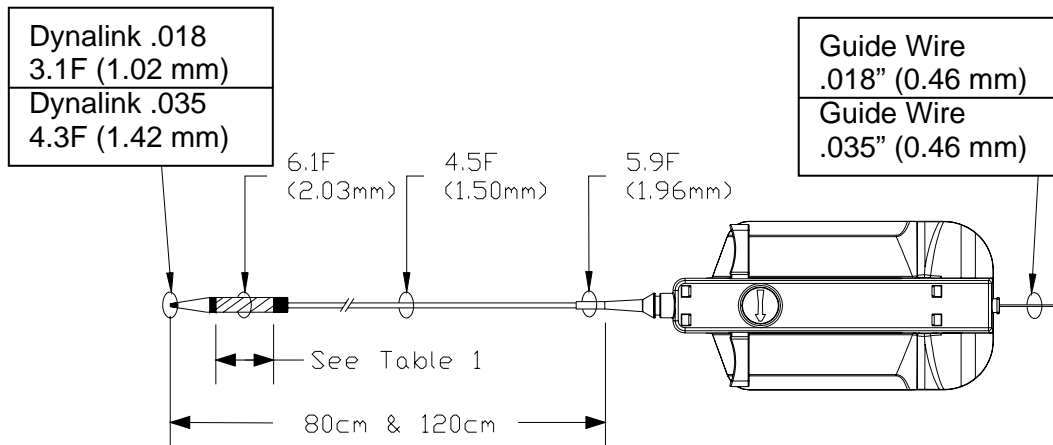
- Table 1: Dynalink Biliary Self-Expanding Stent System – Product Specifications
- Figure 1: .018 & .035 Delivery Systems Schematic for 5.0 - 10.0 mm Stent Diameters
- Figure 2: .035 Delivery System Schematic for 12.0 - 14.0 mm Stent Diameters
- Figure 3: Tip Mandrel Removal
- Figure 4: Deployment Demonstration

### **1.0 DEVICE DESCRIPTION**

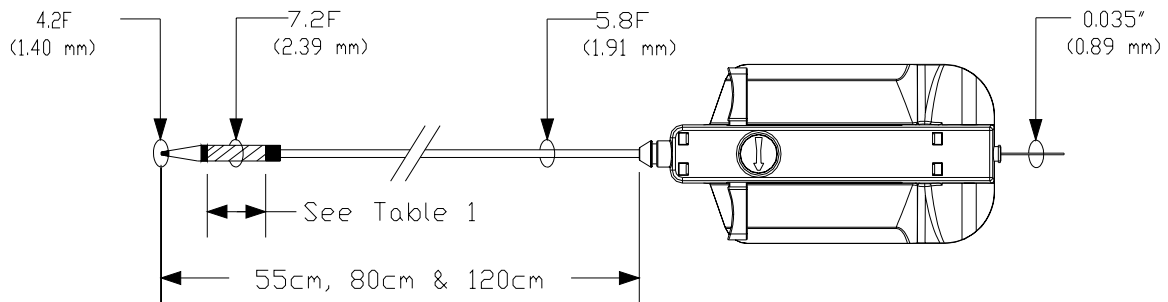
The Dynalink Biliary Self-Expanding Stent Systems include a self-expanding nickel titanium stent that is pre-mounted on an over-the-wire delivery system. The Dynalink .018 Biliary Self-Expanding Stent System utilizes a 0.018" (0.46 mm) guide wire; the Dynalink .035 Biliary Self-Expanding Stent System utilizes a 0.035" (0.89 mm) guide wire. Both systems include radiopaque markers that identify the stent location.

The catheter is comprised of a retractable sheath that covers the stent during delivery, a radiopaque tip, an internal guide wire lumen, and a handle assembly with a safety lock and pullback features. The entire system is shown in Figure 1 and Figure 2 below. With the handle in the unlocked position, retracting the pullback handle deploys the stent.

**Figure 1: .018 & .035 Delivery Systems Schematic for 5.0 - 10.0 mm Stent Diameters**



**Figure 2: .035 Delivery System Schematic for 12.0 - 14.0 mm Stent Diameters**



The Dynalink Biliary Self-Expanding Stent is available in several lengths and diameters, as listed in Table 1. Stents should always be sized to the reference bile duct and should provide stent-to-lumen ratios between 1.1:1 and 1.4:1.

**Table 1: Dynalink Biliary Self-Expanding Stent System – Product Specifications**

Unconstrained Stent Diameter (mm)	Nominal Stent Length (mm)	Sheath Compatibility	Guiding Catheter Compatibility	Reference Bile Duct Diameter (mm)
For .018 and .035 Delivery Systems:				
5.0	28, 38, 56, 80, 100	6F	8F	3.6 - 4.5
6.0	28, 38, 56, 80, 100	6F	8F	4.3 - 5.4
7.0	28, 38, 56, 80, 100	6F	8F	5.0 - 6.3
8.0	28, 38, 56, 80, 100	6F	8F	5.7 - 7.3
9.0	28, 38, 56, 80, 100	6F	8F	6.4 - 8.2
10.0	28, 38, 56, 80, 100	6F	8F	7.1 - 9.1
For .035 Delivery Systems:				
12.0	38, 56, 80	7F	9F	8.6 – 10.9
14.0	38, 56, 80	7F	9F	10.0 – 12.7

## 2.0 HOW SUPPLIED

**Sterile.** Sterilized with E-beam radiation. Non-pyrogenic. This device is intended for single-use only; do not reuse. Do not resterilize. Do not use if the package is open or damaged.

**Contents.** One (1) Dynalink .018 Biliary Self-Expanding Stent System, or  
One (1) Dynalink .035 Biliary Self-Expanding Stent System

**Storage.** Store at room temperature only.

**DO NOT USE IF THE TEMPERATURE INDICATOR ON THE INNER POUCH IS BLACK.**

## 3.0 INDICATIONS

The Dynalink .018 Biliary Self-Expanding Stent System and the Dynalink .035 Biliary Self-Expanding Stent System are intended for palliation of malignant strictures in the biliary tree.

## 4.0 CONTRAINDICATIONS

The Dynalink Biliary Stent System is contraindicated for:

- Stenting a perforated duct where the leakage from the duct can be enhanced by the prosthesis.
- Patients with bleeding disorders.
- Severe ascites.

---

## 5.0 WARNINGS

### DO NOT USE IF THE TEMPERATURE INDICATOR IS BLACK.

The safety and effectiveness of this device for use in the vascular system have not been established.

The long term safety and effectiveness of this device in the biliary system have not been established.

Should **unusual resistance** be felt **at any time** during stricture access or Delivery System removal, the introducer sheath / guiding catheter and stent system **should be removed 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. (See Stent / System Removal – Precautions.)

Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.

The stent is not designed for repositioning or recapturing.

Persons allergic to nickel titanium may suffer an allergic reaction to this implant.

Only physicians familiar with the complications, side effects and hazards commonly associated with biliary stent placement should use this device.

The Dynalink Biliary Self-Expanding Stent System is intended to perform as a system. Do not remove the stent for use in conjunction with other dilatation catheters; do not use the Dynalink Biliary Stent System in conjunction with other stents.

When multiple stents are required, 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 Dynalink Biliary Self-Expanding Stent System, for their intended uses, contraindications, and potential complications.

## 6.0 PRECAUTIONS

Carefully inspect the Dynalink Biliary Self-Expanding Stent System to verify that the device has not been damaged in shipment. Avoid unnecessary handling, which may kink or damage the delivery system.

### 6.1 Stent Handling - Precautions

- **For single use only.** Do not resterilize or reuse. Note the product "Use By" date.

- 
- **Do not remove the stent from its Delivery System.**  
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, mandrel removal, placement over guide wire, and advancement through the guiding catheter hub.

## 6.2 Stent Placement - Precautions

- **Ensure that ALL SLACK IS REMOVED from the Delivery System to enable precise stent placement.**
- Do not expand the stent if it is not properly positioned in the bile duct. (See Stent / System Removal – Precautions.)
- **Do not attempt to pull a partially expanded stent back through the sheath or guiding catheter; dislodgment of the stent from the Delivery System may occur.**
- Stent retrieval methods (use of additional wires, snares and / or forceps) may result in additional trauma or perforation to the bile duct.

## 6.3 Stent / System Removal – Precautions

Should **unusual resistance** be felt **at any time** during either stricture access or removal of the Delivery System post stent implantation, the entire system **should be removed as single unit.**

### When removing the Delivery System as a single unit:

- Do not retract the Delivery System into the guiding catheter or sheath.
- Ensure that the handle is re-advanced to the locked position and the lock is re-engaged.
- Remove the guiding catheter or sheath and delivery system as a single unit.

Failure to follow these steps and / or applying excessive force to the Delivery System can potentially result in loss or damage to the stent and / or Delivery System components.

If it is necessary to retain guide wire position for subsequent biliary access, leave the guide wire in place and remove all other system components.

## 6.4 Post Implant - Precautions

- Exercise great care when **crossing a newly deployed stent** with a guide wire, balloon or Delivery System to avoid disrupting the stent geometry.

---

The Dynalink Biliary stent has been shown to be MRI conditional immediately following implantation.

Non-clinical testing demonstrated that the Dynalink Biliary stent is MR Conditional (poses no known hazards) when scanned under the following conditions:

- Static magnetic field of 3 Tesla or less
- Maximum spatial gradient magnetic field of 3.3T/m
- Maximum whole body averaged specific absorption rate (SAR) of 2.0 W / kg for 15 minutes of imaging

The effect of MRI-related heating for overlapping stents or stents with fractured struts is unknown. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Dynalink Biliary stent.

## **7.0 ADVERSE EVENTS**

Potential complications associated with the use of a biliary endoprosthesis may include:

- Sepsis
- Bile duct occlusion / obstruction
- Tumor overgrowth at the stent ends
- Bile duct perforation potentially leading to infection or death
- Abscess
- Cholangitis
- Peritonitis
- Parenchymal hemorrhage
- Pancreatitis
- Stent migration

## **8.0 CLINICIAN USE INFORMATION**

### **8.1 Stricture Evaluation / Biliary Drainage**

Standard percutaneous transhepatic cholangiography should be performed to assess the biliary tree followed by the passage of a guide wire through the stricture and the placement of an internal / external biliary drainage catheter.

### **8.2 Stricture Treatment**

#### **8.2.1 Stricture Pre-dilatation**

1. Standard percutaneous technique should be used to place the sheath / guiding catheter in the biliary tree. An appropriately sized (0.018" or 0.035") guide wire should be advanced across the stricture and into the common bile duct.
2. Stricture and bile ducts should be pre-dilated. The dilatation balloon diameter should closely match the duct diameter proximal and distal to the stricture to be treated. Withdraw the balloon dilatation catheter while leaving the guide wire in place.

---

### 8.2.2 Inspection Prior to Use

Inspect the temperature indicator on the inner pouch. **Do not use if BLACK.** Remove the Delivery System from its protective packaging. Remove the handle from the package and the shaft from the hoop. Lay the device flat and minimize excessive handling. **THE SHAFT MAY KINK IF NOT HANDLED CAREFULLY.**

Inspect the stent through the clear plastic Delivery System sheath to verify that it has not been damaged during shipment, and that the stent does not overlap the proximal marker.

Ensure that the stent is fully covered by the sheath. Examine the label on the housing assembly and verify that the stent is the correct diameter and length. Do not use if any defects are noted.

### 8.2.3 Materials Required

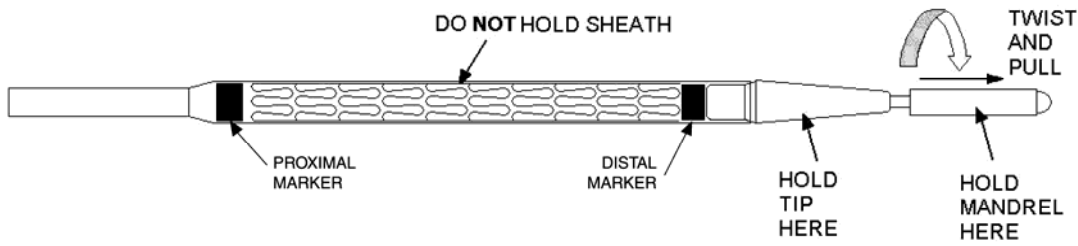
- One guide wire, compatible with the Dynalink Stent System as follows:  
Use a 0.018" (0.46 mm) maximum diameter guide wire with Dynalink .018 Stent System.  
  
Use a 0.035" (0.89 mm) maximum diameter guide wire with Dynalink .035 Stent System.
- Guiding catheter / introducer sheath in the appropriate size and configuration for the selected Stent Delivery System (refer to Table 1)
- Two to three 10-20 cc syringes
- 1,000 u / 500 cc of Normal Saline
- Balloon dilatation catheter
- Torque device
- Guide wire introducer

### 8.3 Delivery System Preparation

**LEAVE THE SAFETY LOCK CLOSED UNTIL THE STENT IS READY TO DEPLOY.**

1. With the tip mandrel in place, inject saline into the lumen through the proximal luer fitting at the end of the housing assembly. Flush until fluid is observed exiting distally near the stent. Hold the distal tip of the Delivery System as in Figure 3. **DO NOT HOLD THE STENT.**
2. Gently **twist and pull** to remove the tip mandrel. If the tip mandrel is not easily removed, do not use the device.
3. Continue flushing until fluid is observed exiting at the distal portion of the tip.
4. Keep the device lying flat to avoid kinking in the shaft.

**Figure 3: Tip Mandrel Removal**



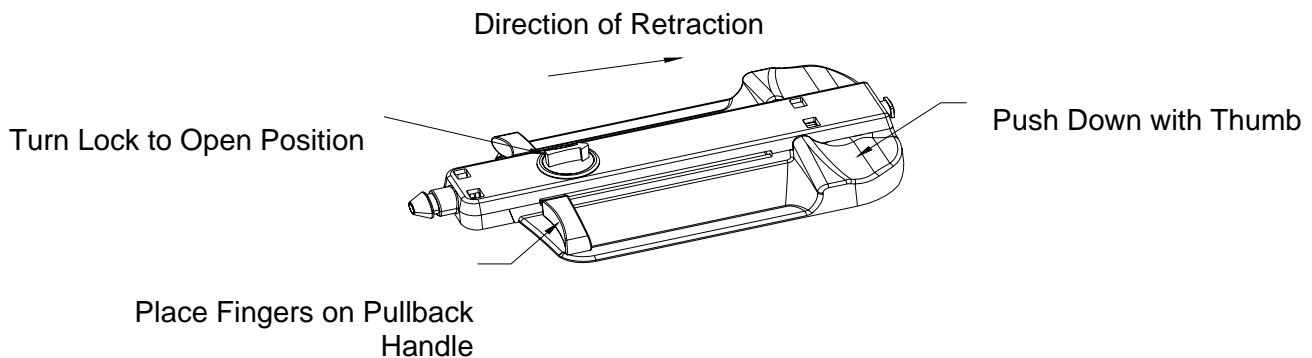
#### 8.4 Delivery Procedure


1. After the pre-dilatation balloon catheter has been removed, **BACKLOAD** the delivery system onto the appropriately sized [0.018" (0.46 mm) or 0.035" (0.89 mm)] guide wire.
2. Advance the Delivery System over the guide wire up to the stricture site. Use the radiopaque markers to locate the stent.

#### 8.5 Stent Deployment

**Figure 4: Deployment Demonstration**

*(With the guide position fixed, deploy with one hand.  
**PUSH DOWN** on thumb groove and retract.)*



- 
1. **Place the housing on a stable surface. Ensure that the Delivery System remains flat and straight. Do not hold the handle. Do not loop the delivery system.**
  2. Turn the safety lock counter clockwise to the deployment position, symbolized by an open padlock icon.  The arrow on the lock will point in the direction the handle will move.
  3. Position the stent using the markers. Confirm the stent position cholangiography. Adjust the stent position if necessary.
  4. **Ensure all slack is removed from the Delivery System before stent deployment.**
  5. The device is designed to be deployed using one hand for handle retraction. Position the thumb in the textured proximal groove and place two fingers on the pullback handle as shown in Figure 4. For 80 and 100 mm stent lengths, the handle includes additional thumb grooves for incremental pullback.
  6. Place the other hand on the sheath on the guiding catheter.

**ENSURE THAT THE SHEATH or GUIDING CATHETER DOES NOT MOVE DURING DEPLOYMENT.**

7. While pressing down with the thumb to avoid any forward motion, retract the pullback handle. **Note:** If significant resistance is encountered during handle retraction before the stent is deployed, re-advance and re-lock the handle and remove the device and sheath or guide.
8. After removal from the stricture, **re-advance the sheath and re-lock the Delivery System** before removal into the sheath or guiding catheter.

## 8.6 Removal Procedure

1. While maintaining guide wire position, withdraw the Delivery System.

**Note:** Should **unusual resistance** be felt **at any time** during either stricture access or removal of Delivery System post-stent implantation, the entire system **should be removed as a single unit**. See Stent / System Removal - Precautions section for specific Delivery System removal instructions.

2. Repeat cholangiography to confirm optimal stent apposition.

**ASSURE STENT IS NOT UNDERDILATED. DO NOT EXPAND THE STENT PAST ITS LABELED MAXIMUM UNCONSTRAINED DIAMETER.**

If necessary, post dilate within the stent. Post dilatation balloon diameters should closely match bile duct reference diameter.

---











## 9.0 PATENTS

This product and its use are protected by one or more of the following patents: United States 4,892,519; 4,938,220; 4,940,062; 4,964,409; 4,981,478; 4,998,923; 5,002,560; 5,034,001; 5,040,548; 5,135,535; 5,159,937; 5,180,368; 5,234,002; 5,263,963; 5,290,230; 5,300,025; 5,300,085; 5,316,706; 5,318,527; 5,334,154; 5,341,818; 5,342,621; 5,348,537; 5,350,395; 5,391,172; 5,411,476; 5,415,637; 5,421,955; 5,423,755; 5,423,885; 5,437,083; 5,441,515; 5,443,458; 5,443,500; 5,451,209; 5,451,233; 5,456,667; 5,458,605; 5,458,613; 5,458,615; 5,476,505; 5,496,275; 5,498,240; 5,507,301; 5,507,768; 5,507,795; 5,514,154; 5,542,925; 5,546,646; 5,549,554; 5,554,120; 5,554,121; 5,556,413; 5,558,643; 5,565,523; 5,695,111; 5,591,197; 5,593,434; 5,603,721; 5,605,696; 5,607,444; 5,618,299; 5,629,077; 5,632,754; 5,632,840; 5,636,641; 5,637,089; 5,637,113; 5,649,977; 5,681,346; 5,695,506; 5,700,286; 5,707,385; 5,709,658; 5,725,549; 5,728,158; 5,735,893; 5,743,875; 5,747,591; 5,749,888; 5,759,192; 5,769,868; 5,780,807; 5,782,855; 5,807,355; 5,816,923; 5,830,181; 5,868,706; 5,868,767; 5,891,090; 5,902,290; 5,931,819; 5,993,460; 6,013,069; 6,013,728; 6,017,364; 6,019,777; 6,027,475; 6,036,707; 6,036,715; 6,056,776; 6,059,748; 6,059,770; 6,061,588; 6,117,106; 6,126,634; 6,126,635; 6,129,707; 6,131,266; 6,139,525; 6,156,047; 6,165,152; 6,165,292; 6,179,810; 6,193,686; 6,200,325 B1; 6,206,852; 6,217,547; 6,221,425; 6,224,803; 6,238,376; 6,248,092; 6,273,911; 6,280,539; 6,299,595; 6,379,369; 6,387,060; 6,551,341; 6,592,570; 6,602,228; 6,602,272; 6,620,192; 6,626,937; 6,679,853; 6,706,053; 6,776,795; 6,846,323; 6,855,161; 6,964,750; 7,128,756; 7,128,758; RE 33,166; RE 34,564  
Other U.S. patents pending. Foreign patents issued and pending.

**Abbott Vascular**  
Santa Clara, CA 95054-2807 USA

CUSTOMER SERVICE  
TEL: (800) 227-9902  
FAX: (800) 601-8874  
Outside USA TEL: (951) 914 -4669  
Outside USA FAX: (951) 914 -2531

### Graphical Symbols for Medical Device Labeling

 Manufacturer	<table border="1"><tr><td>STERILE</td><td>R</td></tr></table> Sterilized Using Irradiation	STERILE	R
STERILE	R		
REF Catalogue Number	 Outer Diameter		
F French Size	 Stent Length		
 Consult Instructions For Use	 Date of Manufacture		
 Guiding Catheter	 Use By		
 Contents (Numeral represents quantity of units inside)	<table border="1"><tr><td>LOT</td></tr></table> Batch Code	LOT	
LOT			
 Do Not Reuse	 Temperature Limitation		

©2007, Abbott Laboratories