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## 8.2 Stricture Treatment

### 8.2.1 Stricture Pre-dilatation

1. Standard percutaneous technique should be used to place an introducer sheath / guiding catheter in the biliary tree. An appropriately sized 0.035 inch (0.89 mm) guide wire should be advanced across the stricture and into the common bile duct.
2. Stricture and bile ducts may need to be pre-dilated with balloon dilatation. Pre-dilatation catheter diameters should closely match the duct diameter proximal and distal to the stricture to be treated. Withdraw the dilatation catheter while leaving the guide wire in place.

### 8.2.2 Inspection Prior To Use

Prior to using the Omnilink .035 Biliary Stent System, carefully remove the system from the package and inspect for bends, kinks, and other damage. Verify that the stent is located between the radiopaque balloon markers. Do not use if any defects are noted.

### 8.2.3 Materials Required

- Guiding catheter / introducer sheath in the appropriate size and configuration for the selected Stent Delivery System (refer to Tables 1-6)
- Two to three 10 - 20 cc syringes
- 1,000 u / 500 cc normal saline
- One 0.035 inch (0.89 mm) diameter guide wire of appropriate length
- 60% contrast diluted 1:1 with normal saline
- One Inflation device
- One Three-way stopcock
- One Torque device (if applicable)
- One Guide wire introducer

## 8.3 Preparation

### 8.3.1 Guide Wire Lumen Flush

1. Remove protective cover from tip.
2. Attach syringe with normal saline to guide wire port.
3. Flush until fluid exits distal tip.

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### 8.3.2 Delivery System Preparation

1. Prepare inflation device / syringe with diluted contrast medium.
  2. Attach inflation device / syringe to stopcock; attach to inflation port.
  3. With tip down, orient Delivery System vertically.
  4. Open stopcock to Delivery System; pull negative for 30 seconds; release to neutral for contrast fill.
  5. Close stopcock to Delivery System; purge inflation device / syringe of all air.
  6. Repeat steps 3 through 5 until all air is expelled.
- Note:** If air is seen in shaft, repeat Delivery System Preparation steps 3 through 5 to prevent uneven stent expansion.
7. If a syringe was used, attach a prepared inflation device to stopcock.
  8. Open the stopcock to the Delivery System.
  9. Leave on neutral.

### 8.4 Delivery Procedure

1. Maintain neutral pressure on inflation device.
  2. Backload Delivery System onto proximal portion of guide wire while maintaining guide wire position across stricture.
  3. Advance Delivery System over guide wire to target stricture. Utilize radiopaque balloon markers to position stent across stricture; perform cholangiography to confirm stent position.
- Note:** If during the process of moving the Delivery System into position you notice the stent has moved on the balloon, do not deploy the stent. The entire system should be **removed as a single unit**. See Stent / System Removal - Precautions section for specific Delivery System removal instructions.
4. Stent is now ready to be deployed.

### 8.5 Stent Deployment

**Caution.** Refer to product label for *in vitro* stent outer diameter, deployment pressure, and RBP.

1. Slowly inflate the delivery balloon to low pressure; hold until balloon inflation is observed both proximally and distally to the stent. Continue balloon expansion to the

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specified stent deployment pressure. Confirm complete expansion of the stent / balloon fluoroscopically. If necessary, the delivery balloon can be used to post dilate the stent to optimize stent apposition.

**Do not exceed RBP. A larger dilatation catheter may be used to dilate the 5 - 7 mm stent to 8 mm maximum. A larger dilatation catheter may be used to dilate the 8 - 10 mm stent to 11 mm maximum.**

2. Deflate the balloon by pulling negative on the inflation device. Ensure that the balloon is fully deflated.

## 8.6 Removal Procedure

1. Ensure balloon is fully deflated.

2. 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.

3. Repeat cholangiography to confirm optimal stent apposition.

**Assure Stent Is Not Underdiluted.** If necessary, post dilate within stent. Post dilatation balloon diameters should closely match bile duct reference diameter.

## 9.0 PATENTS













This product and/or its use are protected by one or more of the following United States patents: 5,421,955; 5,437,083; 5,514,154; 5,546,646; 5,569,295; 5,603,721; 5,649,952; 5,728,158; 5,735,893; 5,759,192; 5,780,807; 6,056,776; 6,066,167; 6,131,266; 6,296,655; 6,369,355; 6,432,133; 6,485,511; 6,568,235; 6,835,059; 6,908,479. Additional patents 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

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### Graphical Symbols for Medical Device Labeling

 Manufacturer	 Inner Diameter
<b>REF</b> Catalogue Number	 Outer Diameter
<b>F</b> French Size	 Stent Length
 Guiding Catheter	 Date of Manufacture
 Consult Instructions For Use	 Use By
 Contents (Numeral represents quantity of units inside.)	 Batch Code
 Do Not Reuse	
 Sterilized Using Irradiation	