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## **Absolute® .035** **Biliary Self-Expanding Stent System**

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

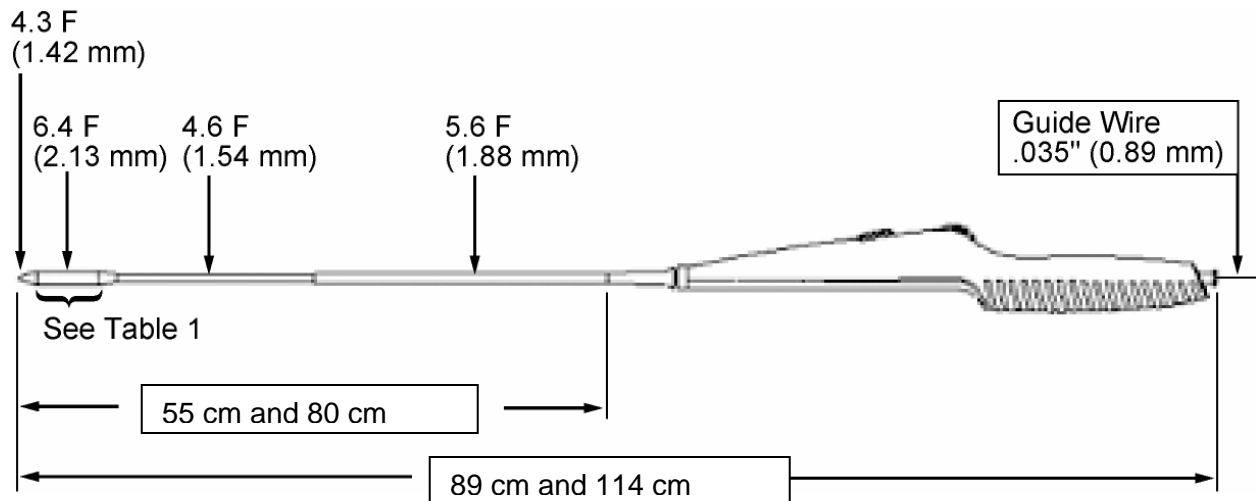
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### **1.0 DEVICE DESCRIPTION**

The Absolute .035 Biliary Self-Expanding Stent System includes a self-expanding nickel titanium stent that is pre-mounted on an over-the-wire Delivery System. A total of 12 (6 at each end) radiopaque markers made of a radiopaque nickel titanium alloy are located at the ends of the stent. The Absolute .035 Biliary Self-Expanding Stent System utilizes a 0.035" (0.89 mm) guide wire. The system includes radiopaque markers that identify the stent location.

The catheter comprises a retractable sheath that covers the stent during delivery, a radiopaque tip, an internal guide wire lumen, a detachable outer jacket, and a handle assembly with a safety lock and retraction features. The entire system is shown in Figure 1 below. With the handle in the unlocked position, rolling back the thumbwheel deploys the stent.



**Figure 1:** Delivery System Schematic for 5.0 - 10.0 mm Stent Diameters

The Absolute .035 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: Absolute .035 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)
5.0	20, 30, 40, 60, 80, 100	6F	8F	3.6 - 4.5
6.0	20, 30, 40, 60, 80, 100	6F	8F	4.3 - 5.4
7.0	20, 30, 40, 60, 80, 100	6F	8F	5.0 - 6.3
8.0	20, 30, 40, 60, 80, 100	6F	8F	5.7 - 7.3
9.0	20, 30, 40, 60, 80, 100	6F	8F	6.4 - 8.2
10.0	20, 30, 40, 60, 80, 100	6F	8F	7.1 - 9.1

## 2.0 HOW SUPPLIED

**Sterile.** Sterilized with E-beam radiation. Non-pyrogenic.

**Contents.** One (1) Absolute .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.**

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### 3.0 INDICATIONS

The Absolute .035 Biliary Self-Expanding Stent System is intended for palliation of malignant strictures in the biliary tree.

### 4.0 CONTRAINDICATIONS

The Absolute .035 Biliary Self-Expanding 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.

This device is intended for single-use only; do not reuse. Do not resterilize. Do not use if the package is open or damaged.

Note the product "Use By" date specified on the package.

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.

Inspect to make sure the outer jacket is attached to the handle. If not, reattach by pushing the outer jacket back into the handle.

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 resheathing or recapturing. The stent is not designed for repositioning once the stent has apposed the duct wall.

Once the stent is apposed to the duct wall, it is not recommended to remove the stent with the delivery system.

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

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

The Absolute .035 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 Absolute .035 Biliary Self-Expanding Stent System in conjunction with other stents.

Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the Absolute .035 Biliary Self-Expanding Stent System, for their intended uses, contraindications, and potential complications.

When multiple stents are required, stent materials should be of similar composition.

## 6.0 PRECAUTIONS

Inspect all product prior to use. Do not use if the package is open or damaged, or if the product is damaged. Avoid unnecessary handling, which may kink or damage the Delivery System.

### 6.1 Stent Delivery System Handling - Precautions

- **Do not remove the stent from its Delivery System** as removal may damage the stent and / or lead to stent embolization. The stent system is intended to perform as a 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.
- If thumbwheel moves prior to unlocking, do not use the unit; unintentional partial or full deployment may occur.
- Do not unlock the handle prior to positioning the stent at the intended location. Failure to follow this instruction could lead to deployment of the stent at an unintended location.
  - Once unlocked, the handle locking mechanism cannot be re-locked.
  - Once unlocked, the retraction sheath may unintentionally release the stent during device manipulation.

### 6.2 Stent Placement - Precautions

- **Ensure that any slack in the Delivery System inside the body is removed by advancing past the stricture and pulling back.**
- 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.**
- The stent is not designed for resheathing or recapturing. The stent is not designed for repositioning once the stent has apposed the duct wall.

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- Once the stent is apposed to the duct wall, it is not recommended to remove the stent with the delivery system.
  - Stent retrieval methods (use of additional wires, snares and / or forceps) may result in additional trauma or perforation to the bile duct.
  - If thumbwheel moves freely in both directions after unlocking, remove the device together with the introducer sheath or guiding catheter as single unit; do not use the unit as unintentional partial or full deployment may occur.
  - Should **unusual resistance** be felt **at any time, including resistance unlocking the handle or rotating the thumbwheel**, during either stricture access or stent deployment, the entire system should be **removed together with the introducer sheath or guiding catheter as a single unit**. Failure to follow these instructions could result in failure to deploy, difficulties with deployment and partial stent deployment or deployment in an unintended location.

### 6.3 Stent /System Removal - Precautions

**Do not attempt to pull a partially-expanded stent back through the sheath or guiding catheter.** The stent is not designed for recapturing. The stent is not designed for repositioning once the stent has apposed the duct wall. Once the stent is apposed to the duct wall, it is not recommended to remove the stent with the delivery system.

Should **unusual resistance** be felt **at any time**, during removal of the Delivery System post stent implantation, the entire system should be **removed together with the introducer sheath or guiding catheter as a single unit**. Failure to follow these instructions could result in failure to deploy, difficulties with deployment and partial stent deployment or deployment in an unintended location.

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

- Do not retract the Delivery System into the guiding catheter or sheath.
- 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 of 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 Absolute .035 Biliary Self-Expanding stent has been shown to be MRI conditional immediately following implantation. Non-clinical testing demonstrated that the Absolute .035 Biliary Self-Expanding 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

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- 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 Absolute .035 Biliary Self-Expanding stent.

## 7.0 ADVERSE EVENTS

Adverse events may be associated with the use of a stent in the biliary tree:

- 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
- Drug reactions to contrast media
- Intervention due to :
  - Stent migration
  - Unintentional placement of stent
  - Partial stent deployment
  - Stretched and/or damaged stents

## 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 (0.035") guide wire should be advanced across the stricture and into the common bile duct.
2. Stricture and bile ducts should be pre-dilated using standard dilatation technique. Pre-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.

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### 8.2.2 Inspection Prior to Use

1. 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.**
2. Inspect the stent through the transparent, amber colored Delivery System sheath to verify that it has not been damaged during shipment, and that the stent does not overlap the proximal marker.
3. 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.
4. Inspect to make sure the outer jacket is attached to the handle. If not, reattach by pushing the outer jacket back into the handle.

### 8.2.3 Materials Required

- One (1) Guide Wire, compatible with the Absolute .035 Biliary Self-Expanding Stent System as follows:

Use a 0.035" (0.89 mm) diameter guide wire with Absolute .035 Biliary Self-Expanding Stent System. Use of an undersized guidewire, with insufficient support, may cause kinking in the Stent Delivery 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

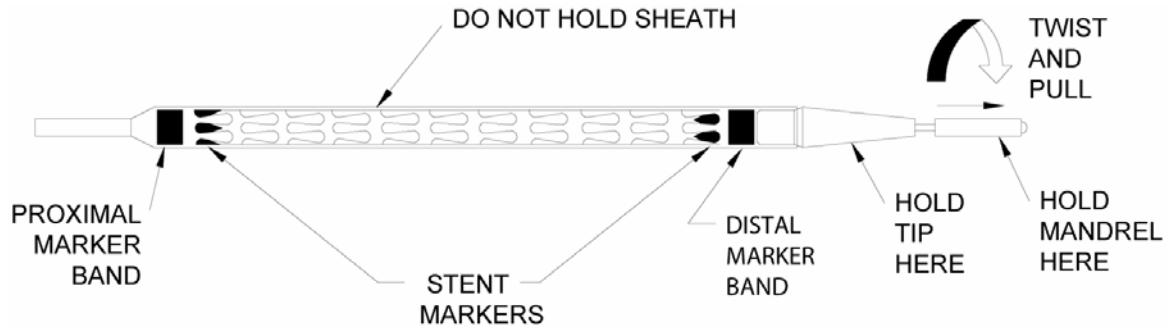
### 8.3 Delivery System Preparation

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

Inspect to make sure the outer jacket is attached to the handle. If not, reattach by pushing the outer jacket back into the handle.

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 and at the distal end of the outer jacket. Hold the distal tip of the Delivery System as in Figure 2.  
**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.

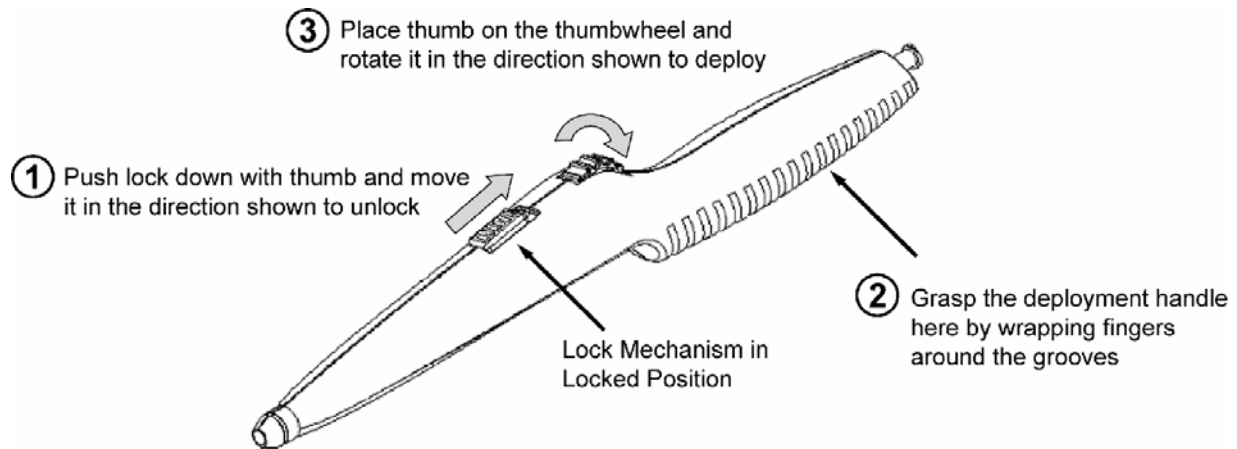


**Figure 2:** Tip Mandrel Removal


#### 8.4 Delivery Procedure

1. After the pre-dilatation catheter has been removed, **BACKLOAD** the Delivery System onto the appropriately sized [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. **Note:** Ensure that the outer jacket is inside the introducer sheath or guiding catheter.

#### 8.5 Stent Deployment



**Figure 3:** Deployment Demonstration

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1. Slide the safety lock proximally to the unlocked position, symbolized by an open padlock icon.  If unit does not unlock, remove **together with the introducer sheath or guiding catheter as single unit**; do not use the unit.
  2. Once unlocked, the lock cannot be relocked.
  3. Advance the Delivery System past the stricture and pull back to remove any slack in the Delivery System inside the body. Position the stent so that the radiopaque stent markers are proximal and distal to the target stricture. Confirm the stent position cholangiographically. Adjust the stent position if necessary.
  4. Place one hand on the proximal end of the handle with the thumbwheel positioned superiorly and the thumb on the thumbwheel.
  5. **ENSURE THAT THE SHEATH or GUIDING CATHETER DOES NOT MOVE DURING DEPLOYMENT.**
  6. Roll the thumbwheel back in the direction of the arrow. **Note:** If inaccuracy is observed during initial deployment (**PRIOR TO STENT APPOSING DUCT WALL**), then the Delivery System position can be adjusted to achieve desired accuracy; if necessary prior to apposing the duct wall, the system (including the stent) can then be removed together with the introducer sheath or guiding catheter as a single unit. **ENSURE THAT THE DELIVERY SYSTEM MARKERS DO NOT MOVE DURING DEPLOYMENT.** If delivery system markers are observed moving distally, pull back using the catheter shaft to maintain delivery system marker position.
  7. Should **unusual resistance** be felt **at any time, including resistance unlocking the handle or thumbwheel rotation**, during either stricture access or stent deployment, the entire system should be **removed together with the introducer sheath or guiding catheter as a single unit**. Failure to follow these instructions could result in failure to deploy, difficulties with deployment and partial stent deployment or deployment in an unintended location.
  8. Remove the Delivery System from the stricture through 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 removal of Delivery System post-stent implantation, the entire system should be **removed together with the introducer sheath or guiding catheter 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/or its use are covered 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; 5,725,572; 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; 6,537,311; 6,568,235; 6,582,460; 6,814,749; and 6,908,479. Additional patents pending.

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### CUSTOMER SERVICE










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## Graphical Symbols for Medical Device Labeling

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

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