

RX Herculink® Plus Biliary Stent System

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

1.0 DEVICE DESCRIPTION

The RX Herculink Plus Biliary Stent System includes:

A flexible, balloon expandable 316L stainless steel stent pre-mounted on a Delivery System.

Two radiopaque markers, located underneath the balloon, which fluoroscopically mark the working length of the balloon.

A marker located approximately 30 cm from the center of the balloon that aids in locating the guide wire exit lumen and facilitating catheter removal and exchange.

The delivery system can be utilized to optimize the stent wall apposition post stent deployment.

Table 1 - *in vitro* Device Specifications

Expanded Stent Diameter (mm)	Stent Length (mm)	Expanded Stent Length (mm)	*<i>in vitro</i> Stent Deployment Pressure (atm)	Rated Burst Pressure - RBP (atm)	Recommended Minimum Guiding Catheter ID (F) / (inches)	Recommended Minimum Sheath Introducer** (F)
4.0	12	11.7	8	14	6 / 0.067"	5
4.5	12	11.6	8	14	6 / 0.067"	5
5.0	12	11.1	8	14	6 / 0.067"	5
5.5	12	11.0	8	14	6 / 0.067"	5
6.0	12	10.7	8	14	6 / 0.067"	5
6.5	12	9.8	8	14	7 / 0.078"	6
4.0	15	14.8	8	14	6 / 0.067"	5
4.5	15	14.6	8	14	6 / 0.067"	5
5.0	15	14.3	8	14	6 / 0.067"	5
5.5	15	14.4	8	14	6 / 0.067"	5
6.0	15	14.2	8	14	6 / 0.067"	5
6.5	15	13.7	8	14	7 / 0.078"	6
7.0	15	13.8	8	14	7 / 0.078"	6
4.0	18	17.7	8	14	6 / 0.067"	5
4.5	18	17.6	8	14	6 / 0.067"	5
5.0	18	17.4	8	14	6 / 0.067"	5
5.5	18	16.8	8	14	6 / 0.067"	5
6.0	18	16.9	8	14	6 / 0.067"	5
6.5	18	17.3	8	14	7 / 0.078"	6
7.0	18	16.9	8	14	7 / 0.078"	6

* Assure full deployment of the stent (see Clinician Use Manual section Deployment Procedure).

Deployment pressures should be based on stricture characteristics.

** See individual manufacturer specifications for (F) equivalent

2.0 INDICATIONS

The RX Herculink Plus Biliary Stent System is intended for palliation of malignant strictures in the biliary tree.

3.0 CONTRAINDICATIONS

The RX Herculink Plus Biliary Stent System is contraindicated for use in:

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

4.0 WARNINGS

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.

Once fully deployed the stent can not be repositioned.

Persons allergic to 316L stainless steel 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 RX Herculink Plus Biliary Stent System is intended to perform as a system. The stent should not be removed for use in conjunction with other dilatation catheters, nor should the RX Herculink Plus Biliary Stent System be used in conjunction with other stents.

5.0 PRECAUTIONS

5.1 Stent Handling - Precautions

- **For single use only.** Do not resterilize or reuse. Note product "Use By" date.
- **Do not remove stent from its delivery balloon.**
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during stent system removal from packaging, placement over guide wire and advancement through the guiding catheter hub or introducer sheath valve.
- Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

5.2 Stent Placement - Precautions

- **Do not prepare or pre-inflate balloon prior to stent deployment** other than as directed. Use balloon purging technique described in the 'Clinician Use Manual' section.
- The inflated balloon diameter of the system used to deploy the stent should approximate the diameter of the bile duct. Oversizing of the stent can result in a ruptured bile duct. To ensure full expansion of the stent, the balloon should be inflated to a minimum of nominal pressure
- Do not expand the stent if it is not properly positioned in the bile duct. (See *Stent / System Removal - Precautions.*)
- Balloon pressures should be monitored during inflation. **Do not exceed Rated Burst Pressure (RBP) as indicated on product label.** Use of pressures higher than specified on product label may result in a ruptured balloon with possible bile duct damage or perforation.
- **Do not attempt to pull an unexpanded stent back through the introducer sheath / guiding catheter; dislodgment of the stent from the balloon may occur.**

5.3 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 a single unit.**

When removing the Delivery System as a single unit:

- DO NOT retract the Delivery System into the introducer sheath / guiding catheter.
- Position the proximal balloon marker just distal to the tip of the introducer sheath / guiding catheter.
- Advance the guide wire in the anatomy as far distally as safely possible.
- Secure the Delivery System to the introducer sheath / guiding catheter; then remove the introducer sheath / guiding catheter, guide wire 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.

5.4 Post Implant - Precautions

Great care must be exercised when **crossing a newly deployed stent** with a guide wire or balloon catheter to avoid disrupting the stent geometry.

The Herculink Plus Biliary stent has been shown to MRI conditional immediately following implantation. Non-clinical testing demonstrated that the Herculink Plus 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 Herculink Plus Biliary stent.

6.0 POTENTIAL ADVERSE EFFECTS

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

- 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

7.0 HOW SUPPLIED

Sterile. Sterilized with electron beam radiation. Non-pyrogenic. Do not use if the package is open or damaged.

Contents. One (1) RX Herculink Plus Biliary Stent System, One (1) Protective / Regrooming sheath, One (1) flush tool

Storage. Store in a dark, dry, cool place.

8.0 CLINICIAN USE MANUAL

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 sheath / guiding catheter in the biliary tree. A 0.014" (0.36 mm) diameter guide wire should be advanced across the stricture and into the common bile duct.
2. Stricture and bile ducts should be pre-dilated. Pre-dilatation balloon diameter should closely match the duct diameter proximal and distal to the stricture to be treated.

8.2.2 Stent Inspection Prior To Use

Prior to using the RX Herculink Plus 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

- Introducer sheath / guiding catheter in the appropriate size and configuration for the selected Stent Delivery System (Refer to Table 1).
- 2 – 3 syringes (10-20 cc)
- 1,000 u / 500 cc Normal Saline
- 0.014" (0.36 mm) diameter guide wire of appropriate length
- 60% contrast diluted 1:1 with normal saline
- Inflation device
- Three-way stopcock
- Torque device (if applicable)
- Guide wire introducer

8.3 System Preparation

8.3.1 Guide Wire Lumen Flush

1. Remove protective cover from tip.
2. Flush guide wire lumen with saline until fluid exits guide wire exit notch.

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 Balloon 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 stopcock to Delivery System.
9. Leave on neutral.

8.4 Delivery Procedure

1. Maintain neutral pressure on inflation device.
2. Backload the Delivery System onto the proximal portion of the guide wire while maintaining guide wire position across the 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 Deployment Procedure

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

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

Do not exceed RBP. A larger PTA catheter may be used to dilate the stent. Do not expand the 15 mm and 18 mm stent beyond 8.0 mm. Do not expand the 12 mm stent beyond 7.1 mm.

2. Deflate balloon by pulling negative on inflation device for 30 seconds.

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 UNDERDILATED. 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: 5,040,548; 5,061,273; 5,242,396; 5,300,085; 5,350,395; 5,421,955; 5,437,083; 5,451,233; 5,514,154; 5,546,646; 5,569,295; 5,603,721; 5,649,952; 5,728,158; 5,735,893; 5,759,192; 5,749,888; 5,769,868; 5,780,807; 6,036,715; 6,056,776; 6,066,167; 6,131,266; 6,165,197; 6,296,655; 6,369,355; 6,432,133; 6,485,511; 6,568,235; 6,575,993; 6,589,207; 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

Graphical Symbols for Medical Device Labeling

 Manufacturer	 Sterilized Using Irradiation
 Catalogue Number	 Outer Diameter
 French Size	 Stent Length
 Consult Instructions For Use	 Date of Manufacture
 Contents (Numeral represents quantity of units inside)	 Use By
 Do Not Reuse	 Batch Code

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