
RX Herculink Elite™ Biliary 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 **RX Herculink Elite Biliary Stent System** includes:

- A balloon expandable L605 cobalt chromium alloy stent pre-mounted on the balloon of a rapid exchange (RX) stent delivery system;
- Two radiopaque markers located underneath the balloon which identify the stent position and fluoroscopically mark the working length of the balloon;
- Proximal shaft markers to aid with delivery catheter position, relative to a biliary guiding catheter tip;
- A third 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 Lengths (mm)	<i>in vitro</i>* Stent Deployment Pressure (atm)	Rated Burst Pressure - RBP (atm)	Recommended Minimum Guiding Catheter ID (F) / (inches) / (mm)	Recommended Minimum Sheath Introducer** (F) / (inches) / (mm)
4.0	12, 15, 18	11	14	6 / 0.067 / 1.70	5 / 0.071 / 1.80
4.5	12, 15, 18	11	14	6 / 0.067 / 1.70	5 / 0.071 / 1.80
5.0	12, 15, 18	11	14	6 / 0.067 / 1.70	5 / 0.071 / 1.80
5.5	12, 15, 18	11	14	6 / 0.067 / 1.70	5 / 0.071 / 1.80
6.0	12, 15, 18	11	14	6 / 0.067 / 1.70	5 / 0.071 / 1.80
6.5	12, 15, 18	11	14	6 / 0.067 / 1.70	5 / 0.071 / 1.80
7.0	15, 18	11	14	6 / 0.067 / 1.70	5 / 0.071 / 1.80

* All data provided is based on *in vitro* testing. 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 HOW SUPPLIED

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

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

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

3.0 INDICATIONS

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

4.0 CONTRAINDICATIONS

The **RX Herculink Elite 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

5.0 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 cannot be repositioned.

Persons allergic to L605 cobalt chromium alloy 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 Elite 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 Elite Biliary Stent System** be used in conjunction with other stents.

The safety and effectiveness of multiple overlapping stents have not been established. However, when multiple stents are required, stent materials should be of similar composition.

6.0 PRECAUTIONS

6.1 Stent Delivery System 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 the packaging, placement over a guide wire and advancement through a guiding catheter or introducer sheath.
- 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.

6.2 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.
- Implanting a stent may lead to dissection of the duct distal and/or proximal to the stent and may cause acute closure of the duct requiring additional intervention (surgical intervention, further dilatation, placement of additional stents, or other).
- Do not expand the stent if it is not properly positioned in the bile duct. (See *Stent / System Removal - Precautions.*)

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- 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.

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 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.

6.4 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 Elite Biliary stent** has been shown to be MRI conditional immediately following implantation. Non-clinical testing demonstrated that the **Herculink Elite Biliary stent** is MRI 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 3.3 T / m
- Maximum whole body averaged specific absorption rate (SAR) of 2.0 W / kg for 15 minutes of MR 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 Elite Biliary stent.**

7.0 POTENTIAL ADVERSE EVENTS

Potential complications associated with the use of a biliary stents 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
- Intervention due to:
 - Stent migration
 - Unintentional placement of stent
 - Partial stent deployment
 - Damaged stents

8.0 CLINICIAN USE INFORMATION

8.1 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

8.2 Stent Inspection Prior To Use

Prior to using the **RX Herculink Elite 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.

8.3 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.

8.4 Stricture Pre-dilatation

1. Standard percutaneous technique should be used to place an introducer 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 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.

8.5 Guide Wire Lumen Flush

1. Remove the protective cover from tip.
2. Using the flush tool, flush the guide wire lumen with normal saline until fluid exits the guide wire exit notch.

8.6 Stent Delivery System Preparation

1. Prepare an inflation device / syringe with diluted contrast medium.
2. Attach the inflation device / syringe to the stopcock; attach to the inflation port.
3. With the tip down, orient the Delivery System vertically.
4. Open the stopcock to the Delivery System; pull negative for 30 seconds; release to neutral for contrast fill.
5. Close the stopcock to the Delivery System; purge the inflation device / syringe of all air.
6. Repeat steps 3 through 5 until all air is expelled. **Note:** If air is seen in the 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 the stopcock to the Delivery System, leave on neutral.

8.7 Stent Delivery Procedure

1. Wipe the exposed guide wire with normal saline.

2. Maintain neutral pressure on inflation device.
3. Backload the Delivery System onto the proximal portion of the guide wire while maintaining guide wire position across the stricture.
4. Advance the Delivery System over the guide wire to target stricture. Utilize radiopaque balloon markers to position the 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.

5. The stent is now ready to be deployed.

8.8 Stent Deployment Procedure

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 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 stent. Do not expand the 4.0 mm - 6.0 mm diameter stent beyond 7.0 mm. Do not expand the 6.5 mm - 7.0 mm diameter stent beyond 8.0 mm.

2. After stent deployment, draw negative pressure on the inflation device for 30 seconds or until the delivery balloon is fully deflated.
3. Return the inflation device to neutral pressure to allow the balloon to refold during removal through the guide catheter.
4. With the inflation device on neutral pressure, carefully withdraw the delivery catheter with the guide wire remaining across the stricture.

Note: Should **unusual resistance** be felt **at any time** during either stricture access or removal of an undeployed stent, the Stent System, guide wire and guiding catheter should be **removed as a single unit**. See *Stent / System Removal – Precautions* section for specific removal instructions.

5. Confirm optimal stent apposition using standard cholangiographic techniques. If necessary, post dilate within the stent. Post dilatation balloon diameters should closely match bile duct reference diameter.

9.0 REFERENCES

The physician should consult current literature on current medical practice on balloon dilatation.

10.0 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; 5,501,227; 5,514,154; 5,546,646; 5,569,295; 5,603,721; 5,649,952; 5,685,312; 5,728,158; 5,735,893; 5,738,674; 5,749,888; 5,759,192; 5,766,238; 5,769,868; 5,780,807; 5,916,234; 6,036,715; 6,056,776; 6,066,167; 6,066,168; 6,131,266; 6,165,197; 6,296,655; 6,309,412; 6,369,355; 6,419,693; 6,428,568; 6,432,133; 6,482,166; 6,485,511; 6,511,504; 6,568,235; 6,575,993; 6,585,657; 6,589,207; 6,596,022; 6,620,193; 6,629,991; 6,651,478; 6,689,159; 6,702,750; 6,736,843; 6,827,734; 6,835,059; 6,840,081; 6,908,479; 6,921,411; 7,060,218. Additional patents pending.

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CUSTOMER SERVICE













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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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