

## Megalink® Biliary Stent

### 1.0 DEVICE DESCRIPTION

The Megalink Biliary Stent is a flexible, balloon expandable 316L stainless steel stent used to maintain patency of a major bile duct obstructed by tissue of an impinging tumor. The stent is designed to be hand crimped onto a balloon delivery catheter and expanded by balloon inflation. The stents are supplied in a variety of lengths and diameters. The *in vitro* test data on the final stent lengths at various expanded diameters are tabulated in Table 1.

**Table 1. Megalink Biliary Stent Product Specifications \***

Length	Deployed Diameter Range	Expanded Stent Diameter (mm)	Expanded Stent Length (mm)	Recommended Catheter *	Recommended Minimum Sheath Introducer*
18 mm	6.0 mm – 8.0 mm	6.0	16.7	OPTA 5 **	8F
		7.0	16.6	OPTA 5	8F
		8.0	16.3	OPTA 5	8F
28 mm	6.0 mm – 10.0 mm	6.0	27.7	OPTA 5	8F
		7.0	27.5	OPTA 5	8F
		8.0	26.8	OPTA 5	8F
		9.0	25.9	See note	8F
		10.0	24.7	See note	8F
38 mm	6.0 mm – 10 mm	6.0	36.4	OPTA 5	8F
		7.0	35.8	OPTA 5	8F
		8.0	35.3	OPTA 5	8F
		9.0	34.4	See note	8F
		10.0	32.8	See note	8F
58 mm	6.0 mm – 10 mm	6.0	55.9	OPTA 5	8F
		8.0	54.8	OPTA 5	8F
		10.0	51.5	OPTA 5	8F

\* All data provided is based on *in vitro* testing with the recommended catheter.

**Note:** The diameter of the stent may be increased post-placement by expanding with a large diameter balloon.

### 2.0 HOW SUPPLIED

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

**CONTENTS.** One (1) Megalink Biliary Stent  
Two (2) crimp mandrels 0.87 mm (0.035") and 0.35 mm (0.014")

**STORAGE.** Store in a dry, dark, cool place.

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### 3.0 INDICATIONS

The Megalink Biliary Stent is indicated for the palliation of malignant strictures in the biliary tree.

### 4.0 CONTRAINDICATIONS

Stenting a perforated duct where the leakage from the duct can be enhanced by the prosthesis.

### 5.0 WARNINGS

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

This device is designed and intended for ONE TIME USE ONLY. DO NOT RESTERILIZE AND / OR REUSE.

Use the stent prior to the “use by” date specified on the package.

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

The maximum balloon inflation pressure used to deploy the stent must not exceed the rated burst pressure specified in the balloon manufacturer’s instructions. Use of a pressure-monitoring device is recommended to prevent overpressurization.

Should unusual resistance be felt at any time during either stricture access, or removal of an undeployed stent, the balloon catheter, stent, and wire should be removed as a single unit.

Stenting across a major bifurcation may hinder or prevent future endoscopic access or procedures.

The Megalink Biliary Stent has been shown to be MRI conditional immediately following implantation. Non-clinical testing demonstrated that the Megalink 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 Megalink Biliary Stent.

### 6.0 PRECAUTIONS

Carefully inspect the Megalink Biliary Stent prior to use to verify that the stent has not been damaged in shipment and that the device dimensions are suitable for the specific procedure. Take care to avoid unnecessary handling.

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.

Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the Megalink Biliary Stent, for their intended uses, contraindications, and potential complications.

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## 7.0 OPERATOR'S MANUAL

### 7.1 Stent Inspection Prior To Use

Prior to using the Megalink Biliary Stent, remove the stent from its protective packaging and carefully inspect the stent to verify that the stent has not been damaged in shipment and that the device dimensions are suitable for the specific procedure. Do not use if any defects are noted.

### 7.2 Materials Required

Quantity	Material
	PTA catheter of appropriate diameter and length for the chosen stent
	Introducer in the appropriate size and configuration
2 - 3	10 - 20 cc syringes
1,000 u/500 cc	Normal Saline
1	Compatible length and diameter guide wire
	60% contrast diluted 1:1 with normal saline
1	Inflation device
1	Three-way stopcock
1	Torque device if desired
1	Guide wire introducer

### 7.3 Preparation

#### 7.3.1 Site Access

Step	Action
1	Perform a careful cholangiogram recommended to delineate the extent and exact location of the obstruction.
2	The transhepatic tract is accessed through a routine transhepatic or endoscopic approach, ensuring the entry site into the bile duct is peripheral enough to place the stent.
3	A sheath is inserted.
4	Access to the stricture is obtained by negotiating a supportive guide wire into the bile duct and across the stricture.

#### 7.3.2 Stricture Preparation

Step	Action
1	Predilate the obstruction with an appropriate size dilatation catheter.
2	Withdraw the dilatation catheter leaving the guide wire in place.

## 7.4 Stent Loading

Step	Action
1	To deliver the stent, select a dilatation catheter of appropriate diameter and length and prepare it per the manufacturer's instructions.
2	Inflate the dilatation catheter to nominal pressure and then deflate. Regroom the balloon using the regrooming sheath packaged with the PTA catheter. A smoother balloon profile may be obtained by a rapid inflation (2 - 4 atm) and deflation of the balloon while the balloon is sheathed. (If the balloon was initially used to dilate the stricture, regroom the balloon as per above.)
3	The stent is packaged on a mounting sheath for ease of loading onto the delivery catheter. Gently twist and pull the handle to remove the protective cover.
4	With the balloon on negative, insert the distal tip of the dilatation catheter into the sheath.
5	Advance the sheath over the balloon tapers.
6	Slide the stent off the sheath and onto the balloon, positioning it equidistant from the balloon markers.
7	Select either a 0.87 mm (0.035") or a 0.35 mm (0.014") crimp mandrel from the stent package. Insert the appropriate size crimp mandrel into the distal tip. (The crimp mandrel is intended to provide inner member support during stent crimping.)
8	Return the delivery catheter to neutral pressure.

### 7.4.1 Stent Crimping

Step	Action
1	Avoid twisting or rolling the stent while crimping.
2	Gently pinch the stent onto the balloon beginning with the distal end first, working proximally.
3	Rotate the stent and balloon 90 degrees and continue to crimp.
4	Assess the stent security on the balloon. Continue crimping until the stent is accurately and securely loaded onto the balloon, and an optimum, smooth profile is attained.
5	Remove the crimp mandrel after the Megalink Biliary Stent has been securely mounted onto the delivery balloon.

## 7.5 Stent Delivery

Step	Action
1	Wipe the exposed guide wire with saline to remove residual blood or contrast medium.
2	Advance the delivery catheter and stent over the guide wire to the treatment site.
3	Position the stent across the stricture.
4	Slowly inflate the delivery balloon to nominal pressure, expanding the stent to optimize stent deployment. Confirm complete expansion of the stent / balloon cholangiography.
5	<b>Do not exceed the Rated Burst Pressure of the PTA catheter.</b>
6	After stent deployment, draw negative pressure until the delivery balloon is fully deflated. Carefully withdraw the delivery catheter on neutral pressure with the guide wire remaining across the stricture.
7	Confirm optimal stent apposition using standard cholangiography.
8	If necessary, the stent can be post dilated with a dilatation catheter to ensure good stent deployment. Do not expand the stent past its labeled maximum diameter. <b>Note:</b> The diameter of the stent may be increased post-placement by expanding with a larger diameter balloon.

## 8.0 REFERENCES

The physician should consult current literature on current endovascular medical practice.

## 9.0 PATENTS

Manufactured under one or more of the following patents. United States, 5,034,001; 5,158,548; 5,242,399; 5,342,621; 5,344,426; 5,369,401; 5,391,172; 5,409,495; 5,415,638; 5,421,955; 5,423,885; 5,437,083; 5,441,515; 5,443,458; 5,443,500; 5,456,667; 5,458,605; 5,458,615; 5,476,505; 5,507,768. Other U.S. patents pending. Foreign patents issued and pending.

\*\* OPTA 5™ is a trademark of Cordis Corporation or an affiliate.

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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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