

INSTRUCTIONS FOR USE – CANADA USE ONLY
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S.M.A.R.T.® Flex Biliary Stent System

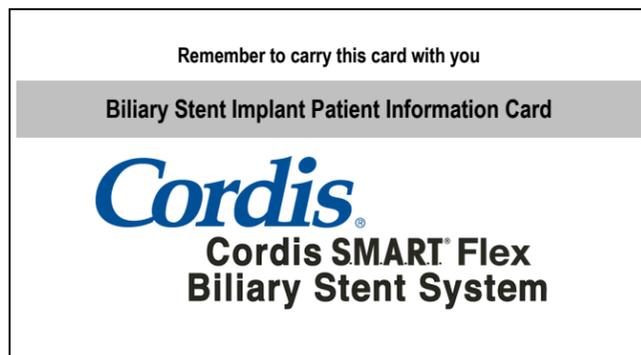
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Sterile: Sterilized by ethylene oxide gas. **Do not use if package is opened or damaged. For single use only. Re-use may increase the risk of injury, inadequate performance and infection. Non-pyrogenic. Radiopaque. MR Conditional.**

The recommendations contained in this document are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

Stent Implant Patient Information Card

Designed for the patients to carry in their wallet for reference along with their healthcare cards. This patient information card provides information pertaining to the stent including the model and lot number of the stent, the date of the procedure and the location of the stent in the implant location. The card also provides manufacturing information and MR Conditions.



For Reportable Events in the USA:

Cordis Corporation
Phone: 800-327-7714
Fax: 888-888-9098
Email: CSubmiss@its.jnj.com

INTENDED USE

The **S.M.A.R.T.® Flex Biliary Stent System** is indicated for use in the palliation of malignant strictures in the biliary tree.

CONTRAINDICATIONS

- Stent of a duct with total biliary occlusion which cannot be crossed by the delivery catheter
- Stenting of a perforated duct where leakage from the duct could be exacerbated by the prosthesis
- Patients with bleeding disorders
- Severe ascites
- Placement in polypoid lesions
- Intra-abdominal abscess
- Biliary obstruction preventing either endoscopic or percutaneous access

GENERAL WARNINGS/PRECAUTIONS

- **The safety and effectiveness of this device for use in the vascular system have not been established.**
- Store at ambient room conditions out of direct sunlight.
- The device is provided STERILE and is intended for single use only. Do Not Resterilize the device and / or reuse the device. Do not autoclave.
- Do not use beyond the "Use By" date.
- Carefully inspect the sterile packaging and device prior to use. Do not use if it appears damaged.
- Do not expose the delivery system to organic solvents.
- If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage to the stent or lumen.
- If resistance occurs during movement through the sheath, carefully withdraw the stent system.
- If resistance is felt when initially retracting the outer deployment sheath, do not force deployment. Carefully withdraw the stent system without deploying the stent.
- Persons allergic to nitinol (nickel titanium) may suffer an allergic reaction to this implant.
- This product should only be used by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for interventional procedures should be employed.
- Do not use power injection systems with the delivery system.
- Use in patients with a history of contrast sensitivity is not recommended unless the patient can be adequately pre-medicated.
- The system is not designed for stent repositioning or recapturing.
- Use caution when crossing a deployed stent with any adjunct device.
- Any use other than those specifically outlined under the indications for use (e.g., intravascular use).
- Removal or repositioning of fully deployed uncovered or bare stents.
- Suspected or impending perforation.

POTENTIAL ADVERSE EVENTS

Potential hazards and side effects include, but are not limited to:

- Infection secondary to contamination of the stent may lead to cholangitis, hemobilia, peritonitis, or abscess.
- Pancreatitis
- Overstretching the duct may result in rupture leading to infection or death.
- Persons with allergic reactions to nickel titanium (Nitinol) may suffer an allergic response to this implant.
- Drug reaction to contrast media
- Tumor overgrowth at the stent ends
- Occlusion due to tumor ingrowth, biliary sludge, or food
- Failed deployment or premature deployment

- Stent not fully expanding or holding shape
- Stent misplacement
- Duodenal perforation
- Cholecystitis
- Intervention due to:
 - Stent migration
 - Unintentional placement of stent
 - Partial stent deployment
 - Stretched and/or damaged stents

DEVICE DESCRIPTION

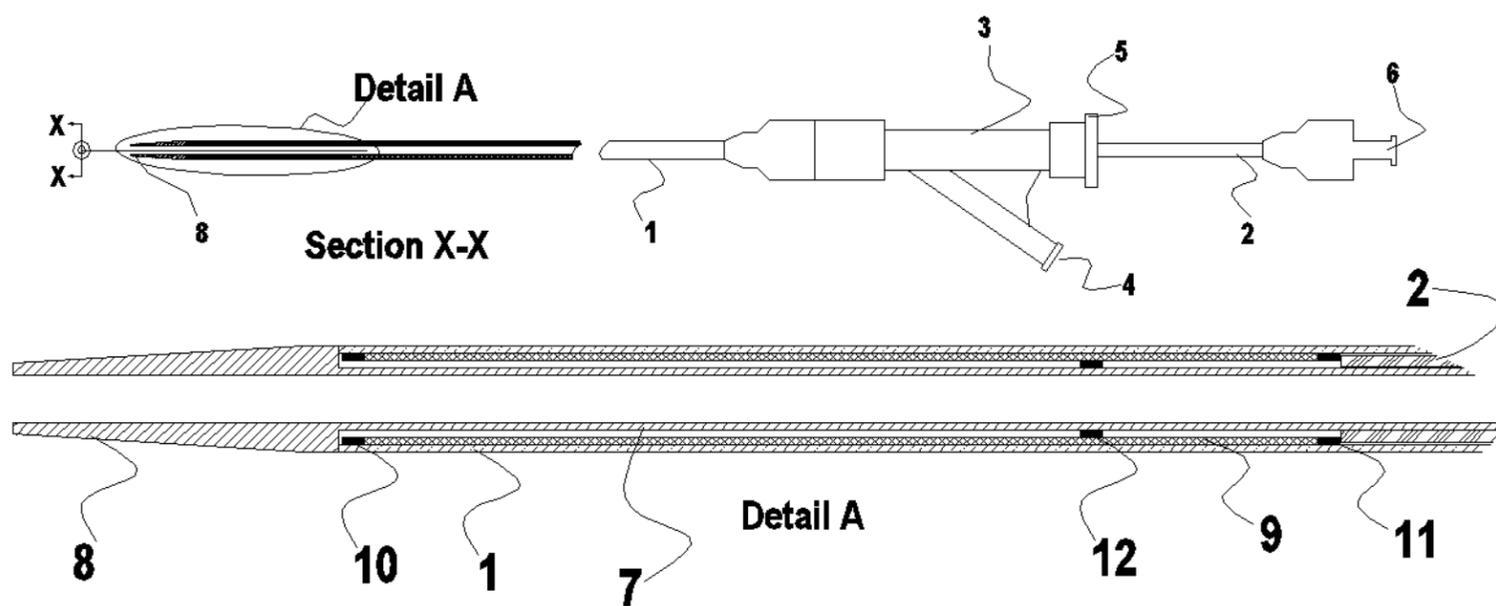
The **S.M.A.R.T.® Flex Biliary Stent System** is a self-expanding stent (**S.M.A.R.T.® Flex Biliary Self-expanding Stent**) pre-mounted and delivered with a simple retractable sheath over-the-wire delivery system. The **S.M.A.R.T.® Flex Biliary Self-expanding Stent** is a nearly fully connected stent made from super elastic nitinol tubing and is constructed through the integration of helically wound struts with helical flexible coils. Both the strut elements and the helical coils provide radial stiffness and an expansion mechanism. The **S.M.A.R.T.® Flex Biliary Self-expanding Stent** is very bendable and will conform with minimal to no fish scaling. Upon deployment, the stent achieves its predetermined diameter and exerts a constant, gentle outward force to dilate the duct stricture. The system is available in both 80cm and 120cm delivery system working lengths.

The **S.M.A.R.T.® Flex Biliary Stent System**, as shown in Figure 1, is composed of a 6Fr outer sheath (1) and a coaxial inner shaft. The inner shaft is composed of a pusher tube (2) and a guidewire tube (7). The pusher tube (2) axially abuts the proximal end of the stent (9) and the guidewire tube is coaxial to the stent (9) and pusher tube (2). The guidewire tube (7) terminates distally in a catheter tip (8) and originates proximally in a Luer hub (6) designed to accept a 0.035" guidewire. The lumen created by the inside diameter of the guidewire tube (7) is flushed prior to the procedure by injecting fluid via the proximal luer hub (6). The 6Fr outer sheath (1) connects proximally to a handle (3) that has a Y connection with female luer (4) and a Tuohy borst valve (5) to provide adjustable frictional force at the proximal portion of the pusher tube (2) and to lock the pusher tube in place prior to deployment. The stent (9) is constrained within the space between the outer sheath (1) and the guidewire tube (7). This space is flushed prior to the procedure by injecting fluid via the Y connection with female luer (4).

Stent positioning about the target stricture is achieved prior to deployment utilizing the distal stent markers (10) and the proximal placement marker (12). These sets of markers indicate the approximate position of the stent after deployment. The proximal stent markers (11) are proximal to the proximal placement marker (12) and indicate the amount the stent will shorten during deployment. The stent system is designed to shorten from proximal to distal during deployment, such that once the distal portion of the stent has been placed at the target location, it will not move during the remainder of the stent deployment and most stent shortening occurs from the proximal end. The distal and proximal radiopaque stent markers (10 and 11) are attached to each end of the stent. The proximal placement marker (12) is a radiopaque band attached to the guidewire tube (7).

For stent deployment, the Tuohy Borst valve (5) must be loosened to allow free movement of the pusher tube (2). To retract the outer sheath (1) and deploy the stent (9), remove any slack in the system, grip the outer sheath (1) and handle (3) with one hand and the pusher tube (2) with the other. Move the outer sheath (1) proximally relative to the pusher tube (2), while holding the pusher tube (2) in a fixed position. The delivery system has a certain amount of compliance and there may be some lag between the proximal movement of the outer sheath (1) / handle (3) and the retraction of the outer sheath (1) at the distal end of the stent (9). The position of the delivery system may need to be adjusted to keep the distal stent markers (10) at the target site during this lag period. Once the distal end of the stent (9) starts to deploy, continue to retract the proximal outer sheath (1) and handle (3) while holding the pusher tube (2) still until the stent (9) is fully deployed and the proximal stent markers (11) have expanded. Note: The proximal placement marker (12) may move during the stent deployment and may not coincide with the location of the proximal stent markers (11).

Figure 1 – S.M.A.R.T.® Flex Biliary Stent System



- | |
|--------------------------------|
| 1 – 6 Fr Outer Sheath |
| 2 – Pusher tube |
| 3 – Handle |
| 4 – Female luer |
| 5 – Tuohy Borst valve |
| 6 – Luer hub |
| 7 – Guidewire tube |
| 8 – Catheter tip |
| 9 – Self-expanding stent |
| 10 – Distal stent markers |
| 11 – Proximal stent markers |
| 12 – Proximal placement marker |

PROCEDURE

1. **Inject Contrast Medium** – Perform a percutaneous cholangiogram using standard technique.
2. **Evaluate and Mark Stricture** – Fluoroscopically evaluate and mark the stricture observing the most distal level of the biliary stricture.
3. **Select Stent Diameter** – Select a stent size diameter according to the reference duct diameter measured and the stent size selection table below. Select a stent length that allows for the proximal and distal aspects of the stent to cover the entire target stricture.

Unconstrained Stent Diameter (mm)	Reference Duct Diameter (mm)
5	3.5-4.5
6	4.5-5.5
7	5.5-6.5
8	6.5-7.5
9	7.5-8.5
10	8.5-9.5

4. **Select Stent Length** – Measure the length of the target stricture to determine the length of stent required. Allow for the area proximal and distal to the tumor to be covered with the stent to protect against impingement from further tumor growth.
 - a. The **Labeled Stent Length** is the unconstrained stent length and the shortest the stent could be.
 - b. The **Maximum Constrained Length** is the length of the stent in the smallest indicated duct diameter. This length is indicated on the system with the *proximal guidewire tube placement marker* (see (12) in Fig. 1).
 - c. The **Minimum Constrained Length** is the length of the stent in the largest indicated duct diameter.

Labeled Stent Length (mm)	Maximum Constrained Length (mm) Per Proximal placement marker	Minimum Constrained Length (mm)
20	22	21
30	33	32
40	45	42
60	66	63
80	88	84
100	110	105
120	132	126
150	165	157

5. Access the treatment site utilizing the appropriate accessory equipment. The stent delivery system is compatible with a 6Fr (or larger) introducer sheath.
6. Introduce an appropriate .035" guidewire through the access catheter or introducer across the distal segment of the target stricture.
7. Pre-dilate the stricture: Generally, no pre-dilation is done with malignant strictures. However, if the physician determines that pre-dilation is necessary, standard dilatation techniques may be used. Remove the dilatation catheter from the patient maintaining stricture access with the 0.035" guidewire. **Warning: During dilation, never expand the balloon such that dissection complications could occur.**
8. **Prepare Stent Delivery System**
 - a. Open the outer box to reveal the pouch containing the stent and delivery catheter.
 - b. After careful inspection of the pouch, looking for damage to the sterile barrier, carefully peel open the outer pouch and extract the inner pouch. Carefully peel open the inner pouch and remove the backboard with carrier tube which holds the stent delivery system. **Warning: DO NOT use if pouch is opened or damaged.**
 - c. Set the backboard with carrier tube on a flat surface. Remove the stent/delivery system from the carrier tube. Examine the device for damage. If it is suspected that the sterility has been compromised or the device is damaged do not use the device.
 - d. If the distal tip (8) is not seated in the outer sheath (1), loosen the Tuohy Borst valve (5) on the handle (3) and retract the pusher tube (2) such that the distal tip (8) will seat in the outer sheath (1). Tighten the Tuohy Borst valve by rotating the valve hub clockwise.
 - e. Check to ensure that the touhy borst valve (5) on the handle is tightened on the pusher tube (2).
 - f. Use a 1-3 cc syringe to flush the outer sheath (1) with sterile saline through the female luer (4) on the handle. Flush until only a few drops of saline exit the distal end of the outer sheath. Complete system flushing may require 2-3 flushings with a 1cc syringe. **Warning: If the outer sheath (1) cannot be flushed do not use the device.**
 - g. Use a 3-10 cc syringe to flush the inner lumen of the guidewire tube with sterile saline through the proximal luer hub (6) attached to the pusher tube (2). **Warning: If the inner lumen of the guidewire tube cannot be flushed do not use the device.**
9. **Introduce the Stent Delivery System**
 - a. Advance the device over the guidewire and through the introducer to the target site. If resistance is met during delivery system introduction, the system should be withdrawn and another system used.
 - b. Under fluoroscopic guidance, position the distal stent markers (10) distal to the target stricture and proximal placement marker (12) proximal to the target stricture.
 - c. Straighten the proximal part of the delivery system as much as possible and keep the handle in a stable position.
 - d. The Tuohy Borst valve (5) on the handle (3) should be loosened, if needed, to allow free movement of the pusher tube (2).
10. **Deploy the Stent**
 - a. Stent deployment must be performed under fluoroscopic guidance.
 - b. Grip the outer sheath (1) and handle (3) with one hand and the pusher tube (2) with the other.
 - c. Move the outer sheath (1) proximally relative to the pusher tube (2), while holding the pusher tube (2) in a fixed position.
 - d. The position of the delivery system may need to be adjusted to keep the distal stent markers (10) at the appropriate location.
 - e. Once the distal end of the stent (9) starts to deploy continue to retract the proximal outer sheath (1) and handle (3) while holding the pusher tube (2) still until the stent (9) is fully deployed and the proximal stent markers (11) have expanded. **Note: The proximal placement marker (12) may move during the stent deployment and may not coincide with the location of the proximal stent markers (11) after deployment.**
 - f. If resistance is felt during retraction of the outer sheath, do not force deployment. Carefully withdraw the stent system without deploying the stent.
11. Under fluoroscopic guidance, withdraw the entire delivery system as one unit, over the guidewire while keeping the guidewire in position, and out of the body. Remove the delivery device from the guidewire. **Warning: Do not forcefully remove delivery system from introducer/sheath – if resistance is met, remove sheath and delivery system as a unit.**
12. Verify full deployment using fluoroscopy. If incomplete expansion exists within the stent at any point along the stricture, post deployment balloon dilatation can be performed at the discretion of the physician. Remove the balloon from the patient. **Warning: Any balloon catheter used for biliary stent dilatation should be indicated for use in biliary stent deployment.**
13. When clinically appropriate, remove the guidewire, sheath, and any other accessory equipment from the body and achieve hemostasis of the access site.

MRI COMPATIBILITY INFORMATION

The **S.M.A.R.T.[®] Flex Biliary Self-expanding Stent (IMPLANT)** was determined to be **MR-Conditional** according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05/08. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 19428.

Non-clinical testing demonstrated that the IMPLANT is **MR Conditional**. A patient with this implant can be scanned safely immediately after placement under the following conditions:

- Normal operating mode of the MR system and use of whole body transmit coil
- Maximum time for WB-SAR scan is 15 min
- 1.5-Tesla/64-MHz MR System reported whole body average SAR value of 3.8-W/kg was associated with a calculated whole body average SAR value of 3.1-W/kg.
- 3-Tesla/128-MHz MR System reported whole body average SAR value of 3.0-W/kg was associated with a calculated whole body average SAR value of 2.8-W/kg.
- Static magnetic field of 3-Tesla or less
- Spatial gradient magnetic field of 720-Gauss/cm or less

MRI-Related Heating

In non-clinical testing of 8x150 and 10x100mm samples, the IMPLANT produced the following maximum temperature rises during MRI performed for 15-min in 1.5-Tesla (1.5-Tesla/64-MHz, Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS) and 3-Tesla (3-Tesla/128-MHz, Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR systems, as follows:

Highest Temperature Change	MRI Condition
+2.7°C	1.5-T/64-MHz
+3.5°C	3-T/128-MHz

Therefore, the MRI-related heating experiments using 8x150 and 10x100mm samples for the IMPLANT at 1.5- and 3-Tesla using a transmit/receive RF body coil at MR system reported a maximum whole body averaged SARs of 3.8-W/kg (i.e., associated with a calorimetry value of 3.1-W/kg) and 3.0-W/kg (i.e., associated with a calorimetry value of 2.8-W/kg), respectively and indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than 3.5°C.

Artifact Information

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 IMPLANT. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	1,585 mm ²	76 mm ²	1,870 mm ²	95 mm ²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

WARRANTY DISCLAIMER

Although this product has been manufactured under carefully controlled conditions, **Cordis Cashel** has no control over the conditions under which this product is used. **Cordis Cashel** therefore disclaims all warranties, both expressed and implied, with respect to the product including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. **Cordis Cashel** shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind **Cordis Cashel** to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

Explanation of symbols on labels and packaging

Manufacturer	Package Content	Date of Manufacture	Do not resterilize	Keep dry	MR conditional	Diameter
Do Not Reuse	Catalog No.	Lot No.	Use By	Keep away from sunlight	Usable length	length
Sterilized with Ethylene Oxide	Caution, Consult Instructions for Use	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	Do not use if package is damaged	Pyrogen free		

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