Cordis
A Cardinal Health company

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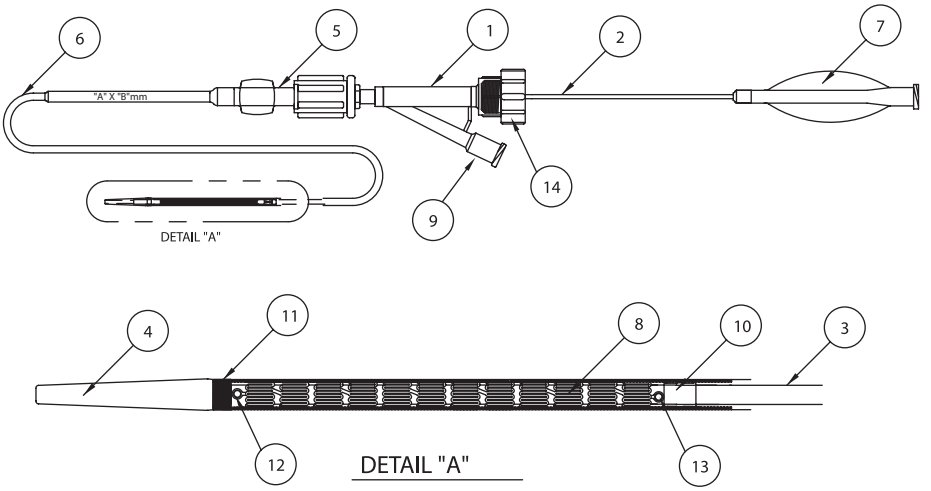
Instructions for Use

Cordis S.M.A.R.T.® Nitinol Stent Transhepatic Biliary Delivery System

Figure 1. S.M.A.R.T.® Nitinol Stent Transhepatic Biliary Delivery System



1. Tuohy Borst Valve
2. Inner Shaft - Stainless Steel Tube
3. Inner Shaft - Stainless Steel Coil
4. Catheter Tip (Distal Wire Lumen)
5. Luer Hub (Outer Sheath)
6. Outer Sheath
7. Luer Hub (Proximal Wire Lumen)
8. **S.M.A.R.T.® Transhepatic Biliary Stent**
9. Y-Connection (on Tuohy Borst Valve)
10. Radiopaque Marker (Inner Shaft Stent Stop)
11. Distal Radiopaque Marker (Outer Sheath)
12. Distal Stent Marker
13. Proximal Stent Marker
14. Proximal Valve (of the Tuohy Borst Valve)

Explanation of symbols on labels and packaging:

	**Use-by date**
	**Lot number**
	**Catalogue number**
	**Do not resterilize**
	**Do not re-use**
	**Non-Pyrogenic**
	**n units per box**
	**Do not use if package is damaged**
	**Keep away from sunlight**
	**Keep dry**
	**Manufacturer**
	**MR Conditional**
	**Caution**

	**Consult instructions for use**
	**Sterilized using ethylene oxide**
	**Caution: Federal (USA) law restricts this device to sale by or on order of a physician.**
	**Recommended Sheath Size**

STERILE. Sterilized with ethylene oxide gas. Nonpyrogenic. Radiopaque. For one use only. Do not resterilize and/or reuse the device. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

I. Device Name
The device brand name is the Cordis **S.M.A.R.T.® Nitinol Stent Transhepatic Biliary System**.

II. Description
The Cordis **S.M.A.R.T.® Nitinol Stent Transhepatic Biliary System** is designed to deliver a self-expanding stent to the biliary tree via a 6F (2.0 mm) sheathed delivery system. The self-expanding stent is composed of a nickel titanium alloy (nitinol). A total of 12 (6 at each end) tantalum radiopaque markers are located on the ends of the stent. The stent is a flexible, fine mesh tubular prosthesis, which expands upon deployment into the biliary duct. Upon deployment, the stent imparts an outward radial force on the luminal surface of the duct to establish patency.

The delivery system, as shown in Figure 1, is comprised of an inner shaft and an outer sheath that are locked together with a Tuohy Borst valve (1). The inner shaft is comprised proximally of a stainless steel tube (2), and distally of a stainless steel coil covered with a polymeric tube (3). The inner shaft terminates distally in a catheter tip (4) and originates proximally in a Luer hub (7) designed to accept a .035" (0.89 mm) guidewire.

The 6F outer sheath (6) connects proximally to the Tuohy Borst valve (1) via a Luer hub (5). The self-expanding stent (8) is constrained within the space between the inner shaft (3) and the outer sheath (6). This space is flushed prior to the interventional procedure by injecting fluid via the Y connection (9) on the Tuohy Borst valve. Stent movement during sheath retraction is restricted by a radiopaque marker (10) connected to the inner shaft. The outer sheath has a radiopaque marker (11) at its distal end.

Stent positioning about the target stricture is achieved prior to deployment utilizing the distal stent markers (12) and the proximal stent markers (13). For stent deployment, the Tuohy Borst valve is unlocked on the inner shaft by a counter clockwise rotation of the proximal valve end (14). Sheath retraction is achieved by grasping the inner shaft (7) in a fixed position and moving the outer sheath proximally relative to the inner shaft. During sheath retraction, prior to stent apposition to the wall, it may be necessary to slightly advance the entire delivery system to maintain stent positioning. Complete deployment of the stent is achieved when the proximal end of the stent and the proximal stent markers (13) visibly appose the duct wall, and the outer sheath radiopaque marker (11) is proximal to the inner shaft stent stop (10).

III. Indications for Use
The Cordis **S.M.A.R.T.® Nitinol Stent Transhepatic Biliary System** is indicated for palliation of malignant neoplasms in the biliary tree.

IV. Contraindications
Contraindications associated with the use of transhepatic biliary endoprostheses include:
- Stenting of a perforated biliary duct where leakage from the duct could be exacerbated by the prosthesis.
- Patients with uncorrected bleeding disorders.
- Stenting of the bile duct in the presence of severe ascites.

V. Warnings
- The safety and effectiveness of this device for use in the vascular system have not been established.
- Persons with allergic reactions to nickel titanium (nitinol) may suffer an allergic response to this implant.
- The Cordis **S.M.A.R.T.** Nitinol Stent Transhepatic Biliary System is intended for single use only. DO NOT resterilize and/or reuse the device.
- This product is designed and intended for single use. It is not designed to undergo reprocessing and resterilization after initial use.
- Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
- The black dotted pattern on the grey temperature exposure indicator, found on the pouch, must be clearly visible. Do not use if entire temperature exposure indicator is completely black as the unconstrained stent diameter may have been compromised.
- Do not use if the pouch is opened or damaged.
- Use the stent system prior to the "Use By" date specified on the package.
- Do not use with Ethiodol or Lipiodol* contrast media.
- Do not expose the delivery system to organic solvents(e.g. alcohol).
- The stent is not designed for repositioning or recapturing.
- Once the stent is partially deployed, it cannot be recaptured using the stent delivery system.
- Stenting across a major bile duct branch could lead to compromised future diagnostic or therapeutic procedures.
- Any secondary expansion of the biliary stent should be performed with a device indicated for biliary stent placement.

VI. Precautions
- The device is intended for use by physicians who have received appropriate training.
- The delivery system is not designed for use with power injection systems.
- Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution.
- Prior to stent deployment, remove all slack from the catheter delivery system (see "Stent Deployment Procedure").
- Fractures of this stent may occur. Fractures may also occur with the use of multiple overlapping stents. In the **S.M.A.R.T.** stent, they have been reported most often in clinical uses for which the safety and effectiveness have not been established. The causes and clinical implications of stent fractures are not well characterized. Care should also be taken when deploying the stent as excessive force could, in rare instances, lead to stent deformation and/or fracture.
- **Store in a cool, dark, dry place.**

VII. Potential Complications
Potential complications associated with the use of transhepatic biliary endoprostheses may include, but are not limited to:
- Bile duct perforation
- Liver abscess
- Pancreatitis
- Parenchymal hemorrhage
- Sepsis/infection
- Sludge occlusion
- Stent migration
- Stent misplacement
- Stent obstruction secondary to tumor ingrowth through the stent
- Tumor overgrowth at the stent ends

VIII. Directions for Use
Procedure
1. Inject Contrast Media
Perform a percutaneous cholangiogram using standard technique.

2. Identify and Mark Stricture
Fluoroscopically identify and mark the stricture, observing the most distal level of the biliary stricture.

3. Select Stent Size
Measure the length of the target stricture to determine the length of stent(s) 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.

* Ethiodol and Lipiodol are trademarks of Guerbet S.A.

Measure the diameter of the reference bile duct (proximal and distal to the stricture). It is necessary to select a stent that has an unconstrained diameter at least 1 mm larger than the largest reference duct diameter to achieve secure placement according to the following Stent Size Selection Table.

Stent Size Selection Table

Duct Lumen Diameter	Unconstrained Stent Diameter	% Length Foreshortening
4.0 - 5.0 mm	6.0 mm	1.2%
5.0 - 6.0 mm	7.0 mm	2.0%
6.0 - 7.0 mm	8.0 mm	3.1%

Refer to product labeling for stent length.
Note: The percent foreshortening of stent length is based upon a mathematical calculation.

4. Preparation of Stent Delivery System
- **a.** Open the outer box to reveal the pouch containing the stent and delivery system.
- **b.** Check the temperature exposure indicator on the pouch to confirm that the black dotted pattern with a grey background is clearly visible. See Warnings section.
- **c.** After careful inspection of the pouch looking for damage to the sterile barrier, carefully peel open the pouch and extract the stent/delivery system from the tray. Examine the device for any damage. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.
- **d.** Flush the Tuohy Borst Y valve with saline using a 3-cc syringe to expel air. Lock the Tuohy Borst valve and continue to flush until saline weeps from the distal catheter end.
- **e.** Flush the guidewire lumen of the stent delivery system with saline using a 10-cc syringe to expel air. Continue to flush until saline flows out of the wire lumen at the distal catheter tip.
- **f.** Evaluate the distal end of the catheter to ensure that the stent is contained within the outer sheath. Do not use if the stent is partially deployed. If a gap between the catheter tip and outer sheath tip exists, open the Tuohy Borst valve and gently pull the inner shaft in a proximal direction until the gap is closed. Lock the Tuohy Borst valve after the adjustment by rotating the proximal valve end in a clockwise direction.

Stent Deployment Procedure

1. Insertion of Introducer Sheath and Guidewire
- **a.** Gain access at the appropriate site utilizing an appropriate size introducer sheath.
- **b.** Insert a .035" (0.89 mm) guidewire of an appropriate length through the introducer sheath to beyond the stricture to be stented.

2. Dilation of Stricture

Generally, no predilation is done with malignant biliary strictures. However, if the physician determines that predilation is necessary, standard dilatation techniques may be used. Remove the dilatation catheter from the patient while maintaining stricture access with the .035" (0.89 mm) guidewire.
Caution: Caution should be taken when dilating the biliary system to minimize potential for perforation.

3. Introduction of Stent Delivery System
- **a.** Ensure that the Tuohy Borst valve, connecting the inner shaft and outer sheath, is locked by rotating the proximal valve end in a clockwise direction to prevent premature stent deployment.
- **b.** Advance the device over the guidewire to the stricture site.
  Note: If resistance is met during delivery system introduction, the system should be withdrawn and another system should be used.
  Caution: Always use an appropriate size introducer sheath for the implant procedure to protect duct and access site.

4. Slack Removal
- **a.** Advance the stent delivery system past the stricture site.
- **b.** Pull back the stent delivery system until the radiopaque stent markers (leading and trailing ends) move in position so that they are proximal and distal to the target stricture site.
- **c.** Ensure the device outside the patient remains flat and straight.
  Caution: Slack in the catheter shaft either outside or inside the patient may result in deploying the stent beyond the target stricture site.

5. Stent Deployment
- **a.** Verify that the delivery system's radiopaque stent markers (leading and trailing ends) are proximal and distal to the target stricture.
- **b.** Ensure that the introducer sheath does not move during deployment.
- **c.** Unlock the Tuohy Borst valve connecting the inner shaft and outer sheath of the delivery system.
- **d.** Initiate stent deployment by retracting the outer sheath while holding the inner shaft in a fixed position. While using fluoroscopy, maintain position of the radiopaque stent markers relative to the targeted stricture site. Watch for the distal radiopaque markers to begin separating. Separation of the distal stent markers signals that the stent is unsheathed. Continue deploying the stent until the distal end of the stent obtains full apposition with the duct wall. Continue deploying the stent until the proximal end of the stent obtains full apposition with the duct wall.
  Note: Failure to maintain a fixed inner shaft position or constraining the catheter shaft during deployment may result in stent compression (shortening) or elongation.
  Note: When more than one stent is required to open the stricture, the more distal stent should be placed first. Efforts should be taken to minimize the stent overlap.

6. Post-deployment Stent Dilatation
- **a.** While using fluoroscopy, advance the outer sheath until the outer sheath marker contacts the catheter tip and withdraw the entire delivery system as one unit, over the guidewire and out of the sheath introducer. Remove the delivery device from the guidewire.
  Caution: The delivery system is not designed for the use of power injection.
- **b.** Using fluoroscopy, visualize the stent to verify full deployment.
- **c.** If incomplete expansion exists within the stent at any point along the stricture, post deployment biliary dilatation can be performed.
  Note: Only areas within the stent length should receive post-deployment dilatation.
- **d.** Select an appropriate size biliary dilatation catheter and dilate the stented stricture with conventional technique. The inflation diameter of the biliary dilatation catheter used for post dilatation should approximate the diameter of the reference biliary duct. Remove the biliary dilatation catheter from the patient.

7. Post Stent Placement
- **a.** Remove the guidewire and sheath.
- **b.** Close the entry wound as appropriate.
- **c.** Discard the delivery system, guidewire, and sheath.

IX. MRI Safety Information

A patient with the S.M.A.R.T. stent may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/identification of device	Cordis S.M.A.R.T. Stents
Nominal values of static magnetic field (T)	1.5 T and 3.0 T
Maximum spatial field gradient (T/m) and (Gauss/cm)	30 T/m (3000 Gauss/cm)
RF excitation	Circularly polarized (CP)
RF transmit coil type	Whole body transmit coil Head RF transmit-receive coil
RF receive coil type	Any receive only coil may be used
Maximum whole body SAR (W/kg)	1.0 W/kg for patient landmarks below the umbilicus 2.0 W/kg for patient landmarks above the umbilicus
Limits on scan duration	15 minutes of continuous RF (a sequence or back to back series/ scan without breaks) followed by a wait time of 10 minutes if this limit is reached
MR image artifact	The presence of this implant produced an image artifact of approximately 9 mm when imaged with a spin echo pulse sequence and a 3.0 T MRI system
If information about a specific parameter is not included, there are no conditions associated with that parameter	

X. How supplied

The Cordis **S.M.A.R.T.® Nitinol Stent Transhepatic Biliary System** is supplied sterile (by ethylene oxide gas) and is intended for ONE USE ONLY.

Also, included in the packaging: One (1) stent implant card

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