

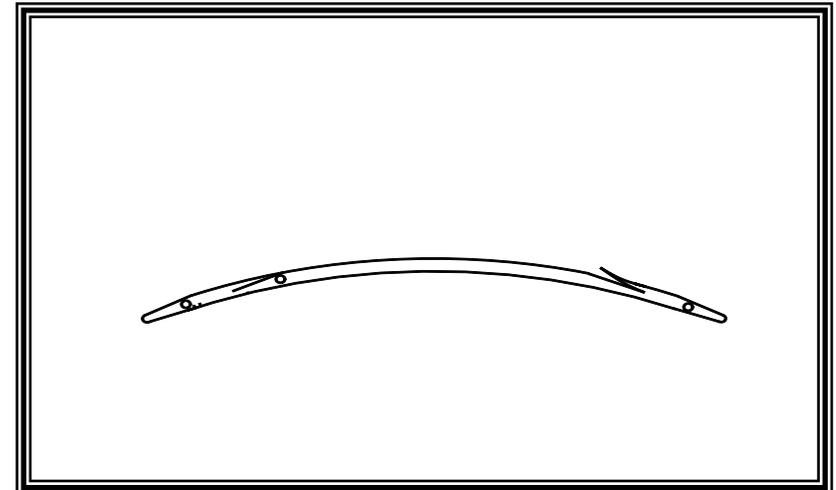


HOBBS MEDICAL, INC.

Precision Instruments for Endoscopy

Biliary Amsterdam Stent Single Use

INSTRUCTIONS FOR USE



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WARNING

Potential adverse effects include but are not limited to: pancreatitis, cholangitis, aspiration, perforation, hemorrhage, infection, sepsis, allergic reaction, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest, trauma to the biliary tract or duodenum, obstruction of the pancreatic duct, stent migration.

WARNING

This device has been validated and is warranted for single-use only. Any re-use, reprocessing or re-sterilization could destabilize the design structure of the device, which could result in device failure, which in turn could result in patient and/or user injury, illness or death. Also, any re-use, reprocessing or re-sterilization could create the risk of cross-contamination of the device, which could result in patient infection or cross-infection.

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COM-1015 REV J

READ CAREFULLY BEFORE USING

SYMBOLS

The meanings of the symbols shown on the package and/or this instrument are as follows:

	Consult Instructions for use		Do Not Use if Package is Damaged
	Use By Date		Manufacturer
	Date of Manufacture		Batch Code
	Do Not Re-Use		Do Not Re-Sterilize
	Catalog Number		Federal Law (USA) restricts this device to sale by or on the order of a physician
	Sterile using Ethylene Oxide		Quantity

SIGNAL WORDS

The following signal words are used throughout this manual:

WARNING

Indicates a potentially hazardous situation, which if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation, which if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

SAFETY

Indications for Use: The stent family products are intended to be used by a physician/trained personnel for endoscopic bile duct/pancreatic duct stent drainage, providing effective relief of pain in patients with ductal obstruction.

CAUTION

Excessive pressure or force applied may cause damage to either the accessory and/or endoscope.

CAUTION

Only the user can evaluate the clinical factors involved with each patient to determine if the use of this device is indicated.

WARNING

A thorough understanding of the technical principles, clinical applications and risks associated with ERCP procedures and with the placement of biliary stents is necessary before using this device.

CONSTRUCTION

Design: Single use Amsterdam Stents are manufactured from a flexible biocompatible material and are MR safe. The 7fr and 10fr with assorted lengths feature retention flanges for easy Stent placement. Compatible with a .035in Guide Wire. This device has been sterilized using Ethylene Oxide.

CONTRAINDICATIONS

Include but not limited to:

- Those specific to ERCP and any procedure to be performed in conjunction with Stent placement
- Inability to pass Guide Wire or Stent through obstructed area

INSTRUCTIONS FOR USE

1. Remove the device from the package. **Save the product lot number for future reference.**
2. Inspect for any functional abnormality. If any irregularities are noted, call Hobbs Medical for a return authorization number.
3. Place positioning sleeve onto the proximal end of the Guide Wire. Insert the distal tip of the Stent, end with the single drainage holes, onto the proximal end of the Guide Wire. Position Stent within the positioning sleeve to ensure that the retention flanges remain flat during introduction into the working channel.
4. Advance the Stent through the working channel using a push catheter until the distal tip is visualized at the distal tip of the Endoscope. A Guide Catheter is required for 10fr or larger stent placement.
5. Ensure proper Stent position before the Stent is deployed. The outer flange will be positioned outside the papilla.

For further information: Please contact Hobbs Medical