

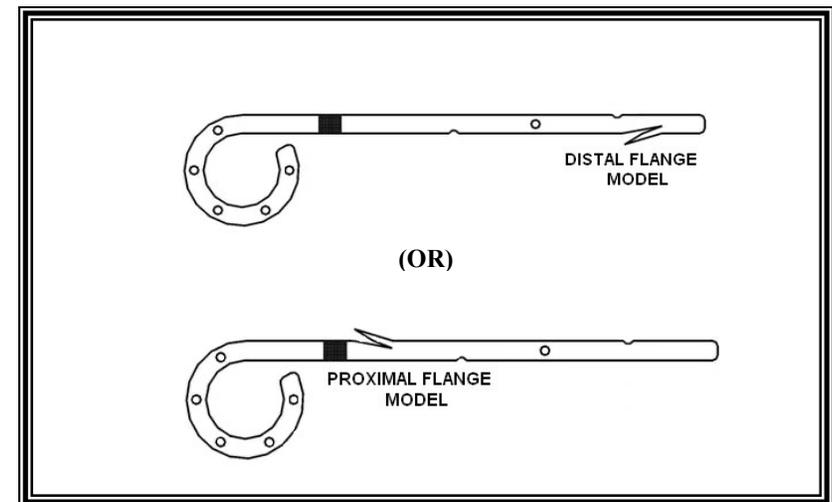


HOBBS MEDICAL, INC.

Precision Instruments for Endoscopy

Freeman Pancreatic Flexi-Stent Single Use

INSTRUCTIONS FOR USE



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WARNING

Potential adverse effects associated with ERCP include but are not limited to: pancreatitis, cholangitis, aspiration, perforation, hemorrhage, infection, sepsis, allergic reaction to contrast medium, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

Potential adverse effects associated with pancreatic stent placement include but are not limited to: trauma to the pancreatic duct or duodenum, 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-1013 REV Q

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

CONSTRUCTION

Design: The single use Freeman Pancreatic Flexi-Stent has been developed from a biocompatible material and is MR safe. The 4fr, 5fr and 7fr with assorted lengths feature a single retention flange, small pigtail radius and an external positioning mark.

Stent Diameter	Recommend Guide Wire Size
4fr	.025 in
5fr/7fr	.035 in

CAUTION Use of a .018 Guide Wire with soft stents could result in buckling.

This device has been sterilized using Ethylene Oxide.

CONTRAINDICATIONS

Include but not limited to:

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

INSTRUCTIONS FOR USE

1. Remove the Stent 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. Insert the distal tip of the Stent (opposite end of pigtail) onto the proximal end of the Guide Wire.
4. Advance the Stent through the working channel until the distal tip is visualized at the distal tip of the Endoscope.
5. When the positioning mark (black stripe) is visualized, ensure proper Stent position. Deploy the Stent with positioning mark and pigtail seated on the outside portion of the pancreatic sphincter.

For further information: Please contact Hobbs Medical