

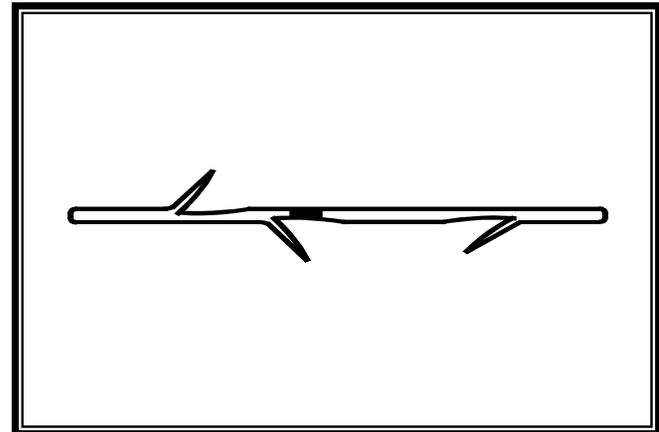


**HOBBS MEDICAL, INC.**

*Precision Instruments for Endoscopy*

# Freeman-Aliperti Straight 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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# 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 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 pancreatic stents is necessary before using the device.

## CONSTRUCTION

Design: The 4fr and 5fr (2cm and 3cm) single use Straight Pancreatic Flexi-Stents are developed from a softer more pliable material and are MR Safe. The 4fr and 5fr Straight Stents provide the physician with a Pancreatic Stent for traversing the pancreatic sphincter. The double external flanges along with the distal anchoring flange are designed to prevent Stent migration.

### Stent Diameter

4fr  
5fr/7fr

### Recommended Guide Wire Size

.025 in  
.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 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. Insert the distal tip of the Stent (end with the single flange), 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 both retaining flanges on the outside portion of the pancreatic sphincter.

**For further information:** Please contact Hobbs Medical