
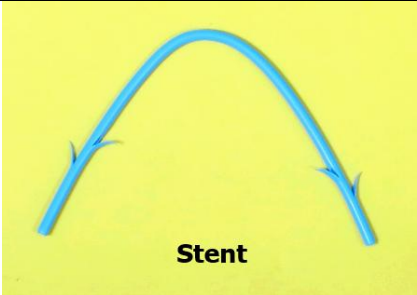




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BANGALORE**

Pancreatic Stents - (With/without Hydrophilic Coated)

Product Name	Packing	Image
Pancreatic stents – with/without Hydrophilic coated	With Packing	
	Without Packing	

INTENDED PURPOSE:

Used to drain obstructed pancreatic ducts. In case of Hydrophilic coated, it is to improve the ease of insertion.

MEDICAL INDICATONS:

- Obstructed pancreatic ducts
- Prevent post-ERCP pancreatitis
- Pancreatic strictures
- Pancreatic leaks/fistulae
- Pancreas divisum.

TARGET PATIENT POPULATION:

Adult- Male and Female

INDENDED USERS:

Gastroenterologist

CLINICAL BENEFITS:

1. Reduce the procedure-related complications
2. Fluoroscopic visualization was excellent
3. Avoidance of repeated endoscopy for stent removal
4. Reduce patient's discomfort
5. Low morbidity and mortality
6. Improvement in quality-of-life
7. Resolve or improve symptoms in chronic pancreatitis patients
8. Effective in treating pancreatic duct leak
9. Safe, effective, and easy to use



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SUMMARY OF SAFETY AND CLINICAL PERFORMANCE REFERRED:

The link for the Summary of Safety and Clinical Performance (SSCP) is provided below:

<https://devoncath.com/Pancreatic-stent-SSCP-2.pdf>

SPECIFICATION:

Parameters	Specifications
Size (F)	5F, 6F, 7F, 8F, 9F and 10F
Length (Cm)	3,5,6,7,8,9,10,12 and 15

Guidewire Compatibility

Type	Straight/J tip/ Zebra Crossing		
Material	Stainless steel 304/Nitinol		
Dimension	Stent Size	Guidewire size (In)	Guidewire length (cm)
	5F	0.035"	80-400
	6F	0.038"	80-400
	7F	0.038"	80-400
	8F	0.038"	80-400
	9F	0.038"	80-400
	10F	0.038"	80-400

SHELF LIFE:

The Pancreatic Stents has a shelf life of 5 years.

IMPLANT CARD:

The required details should be filled in on the enclosed implant card. This card must be handed over to the patient, who should keep it safely for future reference and present it to any gastroenterologist when needed.

RESIDUAL RISKS:

1. Infection
2. Stent Migration/Cholangitis
3. Perforation
4. Toxic to environment
5. Occlusion/ Blockage/ Bleeding

CONTRAINDICATIONS:

- Those specific to ERCP and any procedure to be performed in conjunction with stent placement.
 - Severe cardiopulmonary instability.
 - Perforation of gastrointestinal tract.
 - Known allergy to contrast media.
- Inability to pass guidewire or stent through obstructed area



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- Contraindications specific to the antegrade technique
 - Inaccessible Hepatic Ducts due to congenital anomalies, strictures, or obstructions caused by tumors.
 - Obstructed or Severely Angulated Ducts due to gallstones, strictures tumors, or inflammation in the bile ducts.

PRECAUTIONS:

- Carefully read all instructions for use and product labeling. The device shall only be applied for its intended use, and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.
- All Healthcare professionals is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment. The doctor must be trained in the proper use of the device.

CAUTIONS:

- The sale of this device is restricted by or on the order of a Gastroenterologist.
- Stent placement must be performed only by a qualified gastroenterologist. Use by untrained or unauthorized personnel may result in stent recoiling or migration.

WARNING:

- Pancreatic Stents are intended for single-use only.
- Do not use if the packaging is damaged or if the stent appears cracked, bent, or otherwise defective.
- If the stent is hydrophilic-coated, hydrate it before use. Do not use if the coating appears dry, flaking, or damaged.
- If the stent becomes obstructed, assess its function fluoroscopically or endoscopically, and replace or reposition it as needed.
- The device materials include polyurethane and hydrophilic coating (for coated stents). Patients may experience allergic or hypersensitivity reactions to these materials
- **Duration of Use / Expected Lifetime**
 - The stent should not remain indwelling for more than three (3) months. These stents are not indented as permanent indwelling devices.
 - Do not use device if there is any indication that the sterility of the device has been compromised.
- **Patient Follow-up**
 - Periodic clinical evaluation is recommended to monitor the patient condition and the position/function of the stent.
- **Adverse effects:**
 - Use of this device should be based upon consideration of risk-benefit factors as they apply to your patient. Informed consent should be obtained to maximize patient compliance. Follow up procedures.



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- **Reuse:**
 - Reusing single-use stents can lead to Infection in patients.

UNDESIRABLE SIDE EFFECTS:

A slight risk may be accompanied by procedural complications, such as bleeding and perforation, and problems with the stent, such as deviation, migration, and occlusion

DIRECTIONS FOR USE:

- Open the package carefully to avoid damaging the stent. Incorrect removal of the stent from the package may lead to contamination or product deterioration.
 - This procedure can be performed using either the retrograde or antegrade technique.
 - Select the appropriate stent size for the patient. Using an incorrect size may result in stent displacement or shortening, which can cause occlusion, blockage, or bleeding.
1. Gently ensure full extension of all side flaps.
 2. Load positioning sleeve on to duodenal flap end of stent.
 3. Introduce stent, tapered tip first and positioning sleeve onto guiding catheter and/or pre-positioned guidewire.
 4. Advance guiding catheter and/or pushing catheter in 1-2cm increments until stent is in desired position.
 5. Fluoroscopically and endoscopically confirm desired stent position.
 6. After confirming stent position, gently remove guide wire, and then guiding catheter from endoscope, while maintaining position of the stent with pushing catheter.
 7. Gently remove pushing catheter from accessory channel.

Note: During the implantation procedure, the device is intended to be used in conjunction with ancillary devices such as a guidewire, positioning sleeve/positioner, and guiding catheter to facilitate placement of the stent and achieve the intended clinical function of the device. These ancillary devices are not supplied with this product and must be procured separately as compatible CE-marked devices.

POST IMPLANTATION CARE FOR SURGEON/PATIENT:

Following implantation of a Pancreatic Stent for the drainage of obstructed pancreatic ducts, the patient should be monitored for signs of complications such as abdominal pain, fever, nausea, vomiting, dark urine, or pale stools. The patient should adhere to all prescribed medications, resume a normal diet if not contraindicated, avoid strenuous activities as advised, and attend scheduled follow-up visits to ensure proper stent function and position.

MATERIAL USED:

Polyurethane (PUR)

STERILITY:

These stents are supplied in a package which is sterilized by using Ethylene Oxide. Do not use the stent if the package is damaged. If used it leads to Infection.



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STORAGE CONDITION:

Keep in cool and dry place. store the Stents at temperatures between 5°C to 40°C. Do not expose to direct sun light.

MR SAFE:













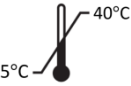





The device is made of non-metallic polyurethane and is safe for use in the MR environment.

DISPOSITION:

The product shall be disposed as per medical device disposal regulation.





NOTE:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	MANUFACTURER		AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	DATE OF MANUFACTURE		USE-BY DATE
	BATCH CODE		COUNTRY OF MANUFACTURE
	STERILIZED USING ETHYLENE OXIDE		DO NOT RESTERILIZE
	DO NOT USE IF PACKAGE IS DAMAGED		SINGLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING INSIDE
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
	TEMPERATURE LIMIT		DO NOT RE-USE
	CONSULT INSTRUCTIONS FOR USE		CAUTION
	MEDICAL DEVICE		UNIQUE DEVICE IDENTIFIER



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SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	PATIENT IDENTIFICATION		PATIENT INFORMATION WEBSITE
	HEALTH CARE CENTRE OR DOCTOR		DATE



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