MEDORAH MEDITEK

MEDORAH® Pancreatic Stent

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

MEDORAH® Pancreatic Stent

Intended Use/ Indications for use:

Intended Use- MEDORAH® Pancreatic Stents are used for treatment of pancreatic duct obstruction caused by malignant and benign tumors. Pancreatic Stents are designed to release the pancreatic juice from the obstructed pancreatic duct and maintaining patency of pancreatic duct.

MEDORAH® Pancreatic Stent is supplied sterile and intended for single use only.

Target Population- The specific group of patients or target patient population is identified based on the medical condition determined by the attending physician. Physician is responsible for diagnosing or treating the patient during an endoscopic procedure, which is the primary procedure itself, aligning with the intended purpose of the medical device.

There are no identified limitations or constraints regarding the patient population or the intended group of patients.

- **Use of the product on minors:**

The product may be applied to minors, provided that the physiological and anatomical conditions of the patient allow for the use of the product.

- **Use of the product on women who are pregnant or breastfeeding:**

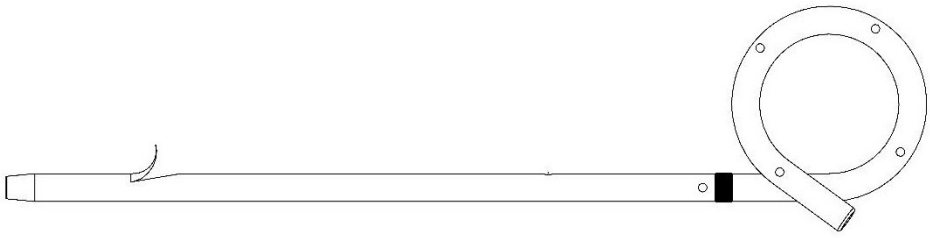
The user is responsible for specifying the indication of product use for pregnant or breastfeeding women, considering the unique physiological and anatomical conditions of each individual patient.

Stent Description

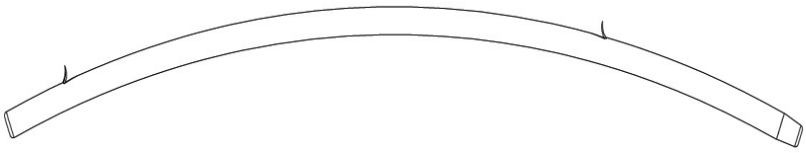
MEDORAH® Pancreatic stent is an implantable plastic stent. These types of stents are cylindrical in shape with holes on it. The Pancreatic stents have tapered ends. The pancreatic stents are available in four sizes with diameters of 5Fr, 7Fr, 8.5Fr and 10Fr.

Two types of pancreatic stents are available and they are as follows:

SINGLE PIGTAIL TYPE



STANDARD (CURVED)



Contraindications

- Those specific to ERCP and any procedure to be performed in conjunction with stent placement
- Inability to pass guidewire or stent through an obstructed area.
- Peritonitis, acute abdomen, e.g., intestinal perforation, ileus
- Sepsis
- Comorbidity, e.g., severe cardiopulmonary diseases and decompensation
- Uncontrollable hemorrhagic diathesis
- Pregnancy
- Recently created gastrointestinal anastomosis.

Complications

Those associated with ERCP include, but are not limited to:

- Acute Pancreatitis
- Cholangitis
- Aspiration
- Perforation
- Hemorrhage
- Infection
- Sepsis
- Allergic reaction to contrast or medication
- Hypotension
- Respiratory depression or arrest

- Cardiac arrhythmia or arrest

Those associated with Pancreatic Stent Placement include, but are not limited to:

- Trauma to pancreatic tract or duodenum
- Obstruction of pancreatic duct
- Stent migration

Warnings

- For single use only. Do not **reuse, reprocess or re-sterilize**. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient diseases.
- If the instrument accidentally becomes dirty before treatment, it must be disposed of immediately. Do not use cleaning agents.
- All components should be carefully checked for compatibility and integrity before use. Do not use defective instruments! If defects occur, dispose of the instrument and replace it with a new one.
- DO NOT use the product after the use before date mentioned on the label.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- DO NOT use the product outside the recommended technical specifications (intended use).
- Wearing protective clothing (gloves, goggles, gown, etc.) is absolutely necessary.
- Never force instruments into the working channel!

Procedure

Choose type and length of stent to be placed.

- Steer the tip of the duodenoscope close to the papilla.
- Insert the guide wire through the operating channel into the pancreatic duct and past the stenosis.

For Non-Pigtail Stents

1. Gently ensure full extension of all side flaps.

For 5 to 7 Fr stents:

2 (a). Introduce stent, tapered tip first onto a pre-positioned guide wire.

(REFER STEPS 3 TO 6 BELOW)

For 8.5 to 10 Fr stents

2 (b) Introduce the guiding catheter into the working channel over a pre-positioned guide wire.

2 (c). Introduce stent, tapered tip first onto a pre-positioned guide wire.

(REFER STEPS 3 TO 6 BELOW)

For Pigtail stents

1. Straighten the pigtail, introduce stent, tapered tip first onto a pre-positioned guide wire.
2. Advance the pushing catheter over guidewire to advance pigtail stent into accessory channel.

(REFER STEPS 3 TO 6 BELOW)

3. Advance the guiding catheter and / or pushing catheter in 1-2 cm increments until stent is in desired position.
4. Confirm the desired position (fluoroscopically and endoscopically).

NOTE (For non-pigtail stents): Inject contrast, if desired to fluoroscopically visualize the stent.

5. After confirming the stent position, gently remove the guide wire, guiding catheter while maintaining the position of stent with pushing catheter.
6. Gently remove the pushing catheter from the working channel of the endoscope.

Post- Procedure Care

- Verification of stent placement is obtained by multiple magnified fluoroscopic examination. Cholangiograms may be necessary to detect and/or rule out other possible strictures within the affected duct. Multiple stent placements may be required to assist in draining additional strictures within the duct.
- The device should not be left indwelling for more than three months or as directed by a physician. This stent is not intended for use as a permanent implant.
- Although stent migration is a rare occurrence, it remains a possibility. Full distal migration occurs when a stent gets dislodged from its original position within the duct and moves into the duodenum.
- If a stent has fully migrated, it will normally pass via the stool. It is possible that the stent can cause internal injury to the duodenal wall and may require removal using various instruments used for foreign body retrieval prior to replacing it with a new stent.

Change of performance

If a device's performance is changed or the intended purpose is lost, the further actions shall be taken according to the medical specialist's decision considering the clinical condition of patients.

Disposal of a used device

The device used must be disposed of according to hospital, local and country regulations. Disposal is the responsibility of the user.

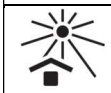
Shelf life of the Product:

The typical lifespan of the product is three years from the manufacturing date.

Storage

Keep the device under normal room temperature and avoid direct sunlight. Follow the first-in-first-out rules and do not use the device out of expiry date.

Explanation of Symbols

	Date of manufacture		Use-By Date
	Catalogue Number		Do Not re-use
	Consult Instructions for use		Caution
	Keep away from sunlight		Batch Code
	Do not use if package is damaged		Manufacturer
	Non-Pyrogenic		Keep dry
	Do Not Resterilize		Sterile using Ethylene Oxide

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by the appropriate procedures. This warranty is in lieu of and excludes all other warranties not expressly set forth herein which are beyond Medorah Meditek Pvt. Ltd. control such as warranties implied to the application of law, sales or specially purpose suitability after handling over, storage, cleaning and sterilization of this product as well as matters related to the patient, diagnosis, treatment, surgical procedures, and any other details. Medorah Meditek Pvt. Ltd. shall not be liable for any incidental, or consequential loss, damage or expense directly or indirectly arising from the use of this product other than the replacement of it. Medorah Meditek Pvt. Ltd. shall neither take any additional responsibility nor authorize such responsibility or duty to other person related to this product.

MEDORAH MEDITEK

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