Instruction for Use

Biliary Stent

Device Description

The Biliary Stent ensures less trauma for tissues Intended for single use, Sterilized. Duration of Contact with the body is not more than 30 days. The configurations available include:

Family	Size(Fr)	Length (Cm)	Type	Colour
Biliary Stent	3.0 5.0 7.0 8.0 8.5 9.0 10.0 11.5 12.0	4 5 6 7 8 9 10 11 12 13 14 15 18	Straight Angle Tip, Straight, Amsterdam C-Type, Amsterdam V- Type, Double Pig Tail, Pancreatic Stent Pig Tail, Single Pig Tail, Biliary Stent Set	Blue/Green

Intended Purpose

A biliary stent is inserted to reduce or eliminate the blockage in bile duct. Once it is in place in the obstructed area, the stent is designed to expand and open the channel so that fluids can continue to move to the intestine.

Intended User

This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Medical Conditions to be Treated

- Relief of biliary obstruction caused by benign or malignant strictures
- Restoration of normal bile flow in patients with obstructive jaundice
- Management of biliary leakage or fistula following surgical procedures
- Palliation of biliary obstruction in patients with cholangiocarcinoma or pancreatic cancer

Performance Characteristics of the Device

The biliary stent is a thin, hollow tube that can be placed in the bile duct to hold the duct open. The smooth surface of the tissue provides less trauma for the tissue. Flap design for better retention. The device is highly radiopaque for better visualization.

Indications

- Used in in treatment of patients with liver, gallbladder, bile duct and pancreatic problems
- Obstructive jaundice from either benign or malignant causes.
- Blockages or stones in bile ducts.

Contraindications

Contraindications include those specific to the Gastro intestinal endoscopic procedure and ERCP and Biliary stenting such as:

- Bleeding Diathesis
- Ascites
- Shock and Acute myocardial infarction.
- Peritonitis
- Acute Perforation
- Fulminant Colitis
- Structural abnormalities of the oesophagus, stomach or small intestine.
- Patients with lesions, inappropriate for stenting.

Precautions, Warnings & Complications

Carefully read all instructions for use and product labelling. Do not use this product without reading and understanding the complete instructions enclosed herein. 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.

Precautions:

- The intended user of the device must be a Gastroenterologist or Hepatologist or under the supervision of endoscopist thoroughly trained in therapeutic endoscopy- ERCP procedure, who is authorized by the Competent Authority of the country in which the physician is practicing.
- Each Physician is responsible for using the appropriate technique and deciding on the indication for use of this device.
- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Device is not recommended for use in patients with the above-mentioned contraindicated conditions.
- Store the Biliary Stent at a temperature between 12-350C and a Humidity range of 30-70%.
- Store in a dry, cool place. Avoid extended exposure to sun light.
- The Stent selection should be based upon various anatomical and lesion considerations.
- Care must be exercised when straightening the pigtail curls in order to avoid kinking or breaking the stent.
- The tapered tip end of the stent or side holes must be positioned in the common bile duct while the other end remains in the duodenum.

Warnings:

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- The device is intended for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient such as bio-contamination due to release of infectious agents from device into the body which further may result in Infection.
- Do not use the device if there is any indication that the sterility of the device has been compromised. If the sterile package is damaged or possibly opened, do not use. Contact "Manufacturer or Distributor" and replace the product.
- Do not reprocess or re-sterilize, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to failure which, in turn, may result in patient injury.
- Check the Stent for any dent, kink or acute bend or damage. If so please do not use it. Avoid stent with acute bend-kink or dent. Check the shape and flaps of stent.

Complications:

- Potential Complications associated with Gastrointestinal Endoscopy- ERCP include but are not limited to perforation, haemorrhage, aspiration, fever, infection, allergic reaction to medication-contrast, hypotension, respiratory depression, or arrest.
- Leakage of bile from sideways of stent. Fluoroscopic exposure and associated complications.

Intended Patient Population

- The device is intended for use in adult patients having the above-mentioned conditions.

Shelf-life

The shelf life of the Biliary Stent is 3 years (Indicated on product label with the following use-by date symbol).

Sterility – This product is Sterile unless the package has been opened or damaged

- The Biliary Stent have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change colour from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct colour.
- Exposure to high levels of Ethylene Oxide may result in residual ETO which leads to Toxic Reaction in the body resulting in tissue damage.
- If the sterile package is damaged or possibly opened, do not use.
- The Biliary Stent are packed single. Product in each pack must be utilized immediately when opened.

Directions for Use

- First place a guidewire through the endoscope instrument channel in to the Bile duct, then slide the stent over the wire and push it with the pusher into the Bile duct. Introduce stent with tapered tip first and pigtail straightener onto pre-positioned guidewire until straightener reaches second curl.
- The pigtail straightener with shaft of stent to tapered tip end is used to straighten the pigtail curl.
- Advance pushing catheter over guidewire to advance pigtail stent into accessory channel.
- Advance guiding catheter and pushing catheter in 1-2 cm increments until stent is in desired position.
- Fluoroscopically and endoscopically confirm desired stent position.
- After confirming stent position, gently remove guidewire, then guiding catheter from endoscope while maintaining position of stent with pushing catheter.
- Gently remove pushing catheter from accessory channel.

Removal Instructions

Retrieve cystoscopically by gently pulling on Stent or retrieval line with grasping forceps or equivalent. If resistance is encountered during removal of the Stent, stop and determine cause of resistance before proceeding.

Disposal Instructions

Dispose of all equipment in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
REF	Catalogue Number	UDI	Unique Device Identifier		Do not re sterilize		Country of Manufacture	MD	Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
LOT	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use	75% 30%	Humidity Limit
STERILE EO	Sterilized using ethylene oxide		Consult Instructions for Use	35 °C 12 °C	Temperature Limit		Do Not Use if Package is Damaged		

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Bibliography

- Single Use Medical Device: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices – Information to be supplied by the manufacturer.