

# Instruction for Use of Biliary Plastic Stent Set

## **WARNINGS:**

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1. **For single use only.** Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, reprocessed or resterilized.
2. Do not use this device for any purpose other than the intended use.
3. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. If you cannot see the distal end of the insertion portion in the endoscopic field of view, do not use it. Insertion without clear endoscopic field of view could cause patient injury, such as perforation, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.

## DEVICE NAME

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Biliary Plastic Stent

Biliary Plastic Stent Set

### 【CATALOGUE NUMBER】

#### a) Biliary Plastic Stent

BPDS	- X	X	X	X	X	- XX	XX
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)

- (1) BPDS: Product code
- (2) Plastic stent material (4:TPU)
- (3) Plastic stent shape (1: Straight; 3: Side bend; 4: Center bend)
- (4) Proximal shape (0:O-shape pigtail; 1:Single side flap; 9:Q-shape pigtail)
- (5) Distal shape (0:O-shape pigtail; 1:Single side flap; 9:Q-shape pigtail)
- (6) Side hole (3: Have holes all over the stent and no flap holes; 4: Have side holes and flap holes at both ends; 6: Have holes all over the stent and have flap holes)
- (7) Plastic stent diameter (07:7Fr; 08:8.5Fr; 10:10Fr; 11:11.5Fr)
- (8) Plastic stent effective length (03:30mm; 04:40mm; 05:50mm; 06:60mm; 07:70mm; 08:80mm; 09:90mm; 10:100mm; 11:110mm; 12:120mm; 13:130mm; 14:140mm; 15:150mm; 16:160mm; 17:170mm; 18:180mm;)

#### b) Biliary Plastic Stent Set

##### b.1)Biliary Plastic Stent Set(Normal)

BPDS	- X	X	X	X	X	- XX	XX	/XX
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

- (1) BPDS: Product code
- (2) Plastic stent material (4:TPU)
- (3) Plastic stent shape (1: Straight; 3: Side bend; 4: Center bend)

- (4) Proximal shape (0:O-shape pigtail; 1:Single side flap; 9:Q-shape pigtail)
- (5) Distal shape (As same as proximal shape)
- (6) Side hole (3: Have holes all over the stent and no flap holes; 4: Have side holes and flap holes at both ends; 6: Have holes all over the stent and have flap holes)
- (7) Plastic stent diameter (07:7Fr;08:8.5Fr;10:10Fr;11:11.5Fr)
- (8) Plastic stent effective length (03:30mm; 04:40mm; 05:50mm; 06:60mm; 07:70mm; 08:80mm; 09:90mm; 10:100mm; 11:110mm; 12:120mm; 13:130mm; 14:140mm; 15:150mm; 16:160mm; 17:170mm; 18:180mm;)
- (9) Introducer working length (22:2200mm)

**b.2)Biliary Plastic Stent Set(Pusher)**

BPDS	- X	X	X	X	X	- XX	XX	/XX
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

- (1) BPDS: Product code
- (2) Plastic stent material (4:TPU)
- (3) Plastic stent shape (1: Straight)
- (4) Proximal shape (0:O-shape pigtail; 9:Q-shape pigtail)
- (5) Distal shape (0:O-shape pigtail; 9:Q-shape pigtail)
- (6) Side hole (3: Have holes all over the stent and no flap holes)
- (7) Plastic stent diameter (07:7Fr)
- (8) Plastic stent effective length (03:30mm; 04:40mm; 05:50mm; 06:60mm; 07:70mm; 08:80mm; 09:90mm; 10:100mm; 11:110mm; 12:120mm; 13:130mm; 14:140mm; 15:150mm)
- (9) Introducer working length (22:2200mm)

## 【SPECIFICATION】

### a) Biliary Plastic Stent

Plastic stent material	Plastic stent shape	Proximal shape	Distal shape	Side hole	Plastic stent diameter D1 (Fr) ( tolerance±0.5mm)	Plastic stent effective length L1(mm) (tolerance±5mm)
4:TPU	1:Straight; 3:Side bend; 4:Center bend	0:O-shape pigtail; 1:Single side flap; 9:Q-shape pigtail	0:O-shape pigtail; 1:Single side flap; 9:Q-shape pigtail	3: Have holes all over the stent and no flap holes; 4: Have side holes and flap holes at both ends; 6: Have holes all over the stent and have flap holes	7(2.33mm), 8.5(2.83mm), 10(3.33mm), 11.5(3.83mm)	30,40,50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150,160,170,180

### b) Biliary Plastic Stent Set

#### b.1)Biliary Plastic Stent Set(Normal)

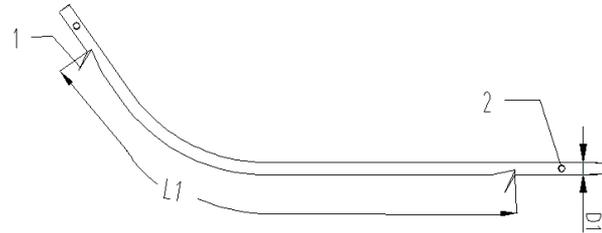
Biliary Plastic Stent					Introducer	
Material	Shape	End shape	Outer diameter D1(Fr) (tolerance±0.5mm)	Effective length L1(mm) (tolerance±5mm)	Outer diameter(Fr) (tolerance±0.5mm)	Working length(mm) (tolerance±50mm)
4:TPU	1:Straight; 3:Side bend; 4:Center bend	0:O-shape pigtail; 1:Single side flap; 9:Q-shape pigtail	7(2.33mm)	30、40、50、60、70、80、90、100、110、120、130、140、150、160、170、180	7(2.33mm)	2200
			8.5(2.83mm)		8.5(2.83mm)	
			10(3.33mm)		10(3.33mm)	
			11.5(3.83mm)		11.5(3.83mm)	

#### b.2)Biliary Plastic Stent Set(Pusher)

Biliary Plastic Stent					Introducer	
Material	Shape	End shape	Outer diameter D1(Fr) (tolerance±0.5mm)	Effective length L1(mm) (tolerance±5mm)	Outer diameter(Fr) (tolerance±0.5mm)	Working length(mm) (tolerance±50mm)
4:TPU	1:Straight	0:O-shape pigtail; 9:Q-shape pigtail	7(2.33mm)	30、40、50、60、70、80、90、100、110、120、130、140、150	7(2.33mm)	2200

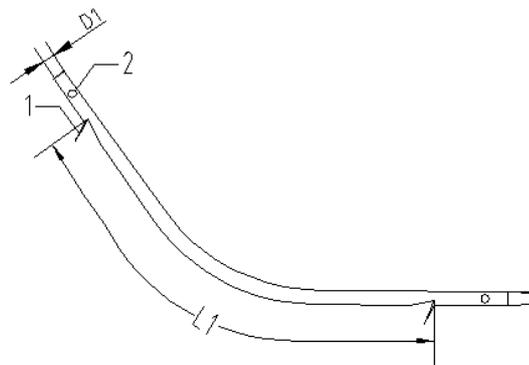
## 【STRUCTURE】

### a) Biliary Plastic Stent



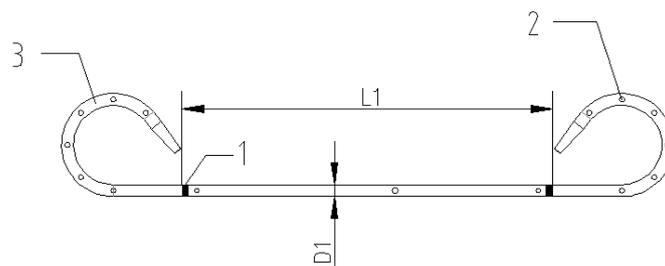
1- Side flap 2- Side hole

Fig. 1 Side bend single side flap plastic stent with side holes and flap holes at both ends



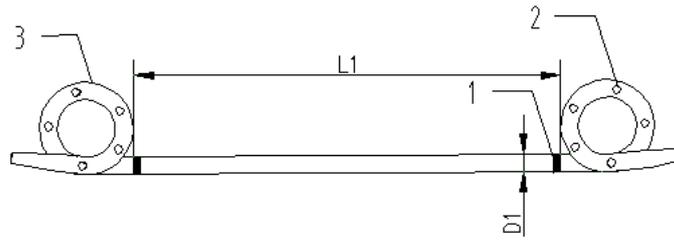
1- Side flap 2- Side hole

Fig. 2 Center bend single side flap plastic stent with side holes and flap holes at both ends



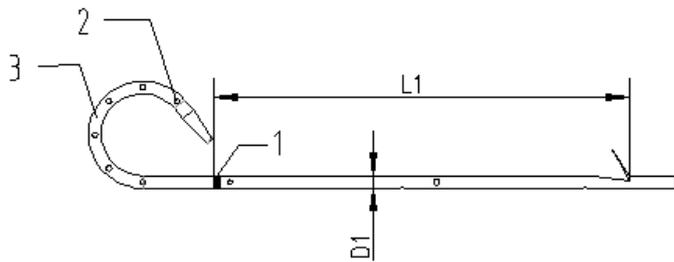
1- Marker 2- Side hole 3- Pigtail

Fig. 3 O-shape double pigtail plastic stent



1- Marker 2- Side hole 3- Pigtail

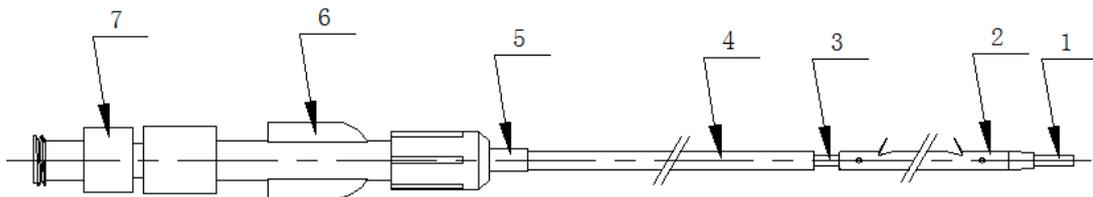
Fig. 4 Q-shape double pigtail plastic stent



1- Marker 2- Side hole 3- Pigtail

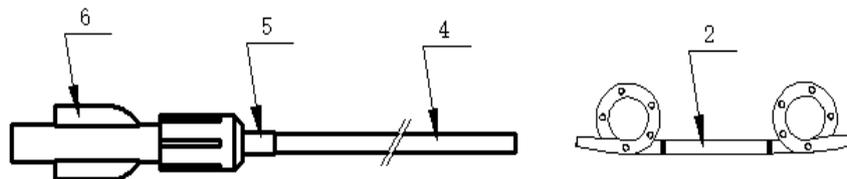
Fig. 5 Single pigtail plastic stent

**b) Biliary Plastic Stent Set**



1.Develop ring;2.Biliary Plastic Stent;3.Inner tube;4.Outer tube;5.Nut gasket(only for 7F);6.Luer connector;7.Transparent knob

Fig. 6 Biliary Plastic Stent Set(Normal)



2.Biliary Plastic Stent;4.Outer tube;5.Nut gasket;6.Luer connector

Fig. 7 Biliary Plastic Stent Set(Pusher)(Only for 7F double pigtail plastic stent)

**【RADIOPACITY INFORMATION】**

### **a) Biliary Plastic Stent**

The Biliary Plastic Stent can be visible on X-ray

### **b) Biliary Plastic Stent Set**

The Biliary Plastic Stent and develop ring of Biliary Plastic Stent Set can be visible on X-ray.

## **【Patient Target Group】**

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The product is intended for adult.

## **【INTENDED USE】**

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This device is used to drain obstructed biliary ducts.

## **【INDICATIONS】**

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- 1.Short term drainage for malignant biliary obstruction (<3 months), including preoperative preparation, and palliative treatment for inoperable patients;
- 2.Benign biliary stricture
  - (1) Patients with multiple bile duct stones or large stones that are difficult to remove, or who are not suitable for surgery;
  - (2) Traumatic or iatrogenic bile duct cicatricial stricture.
  - (3) Biliary stricture caused by sclerosing cholangitis.

Remark: The intended purpose of the device is used for drainage at all stages of malignant biliary obstruction, including preoperative preparation and palliative treatment for inoperable patients, and benign biliary stricture.

## **【CONTRAINDICATIONS】**

Contraindications for this device are those for endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic sphincterotomy (EST), include:

- 1.The device cannot reach the descending duodenum due to technical/mechanical reasons (obstruction etc.);
- 2.The endoscopy cannot be tolerated;
- 3.High risk of bleeding due to coagulopathy;
- 4.Severe allergic reaction to contrast medium;
- 5.Contraindications for anesthesia/sedation;
- 6.Any other conditions the physician judges unsuitable for use.

## **【POTENTIAL COMPLICATIONS】**

- 1.Pancreatitis, cholangitis, hyperamylasemia, hemorrhage, perforation, sepsis, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest, injury to biliary tract and intestinal tr

act, stent obstruction, stent migration, stent break.

2. Complications which are not currently known or observed may be present.

**【INTENDED USER】**

This device is intended for use by physicians who have received ERCP operation training.

**【Clinical Benefit】**

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This device is used to drain obstructed biliary ducts. The Biliary Plastic Stent can drain bile, reduce biliary pressure, relieve obstruction and improve the quality of life of patients.

## PRODUCT MATERIAL SUBSTANCE TABLE

Part name	Overall materials	Hazardous substance to which patients can be exposed		
		CMR/ED	Bisphenol A	Phthalates
Biliary Plastic Stent	TPU	ND	ND	ND
Introducer	PTFE, Ta, PEEK	ND	ND	ND
Remarks: ND=Not detected or less than method detection limit. CMR&ED substances meet the requirements of Medical Device Regulation 2017/745, and the content of CMR&ED substances in concentration is not above 0.1% weight by weight (w/w) The Phthalates and Bisphenol A meet the requirements of REACH EC/1907/2006, and the content of all substances shall not exceed 0.1%.				

## OVERALL QUALITATIVE AND QUANTITATIVE INFORMATION

Implanted Part Name	Material	Content
Biliary Plastic Stent	TPU	100%

## CAUTIONS

1. A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.
2. Patient should be informed and expressed his/her acceptance for the details of the operation and all the potential risks and complications, which may lead to injury, illness or death of the patients.
3. Please read this instruction manual entirely before use.

## NOTES

1. Use of this device restricted to a trained healthcare professional.
2. This device is for single use only. It can be used for only one patient. Do not reuse, reprocess or resterilize.
3. This device can remain in the body no more than 90 days.
4. Refer to package label for minimum channel size required for this device.
5. If Biliary Plastic Stent need to be removed, please using stone basket.
6. A single copy of the instructions for use is provided in a case box. If further copies are requested, please contact Micro-Tech, we will provide free of charge.
7. Any serious incident that occurs in relation to this device should be reported to the manufacturer and relevant local regulatory authority.

8. Micro-Tech 's plastic stent can only be released with Micro-Tech 's Biliary Plastic Stent Introducer.

9. If you need more clinical information about the product, you can view the Summary of Safety and Clinical Performance (SSCP). It will be uploaded to the European Database on Medical Devices (Eudamed) (link: <https://ec.europa.eu/tools/eudamed>), where it is linked to the Basic UDI-DI.

## HOW SUPPLIED

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The device is supplied STERILE.

## STORAGE

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Store the device in a cool, dark and dry place, and do not expose the package to organic solvents, ionizing radiation or ultraviolet light.

Storage condition: temperature limit: 10°C-25°C, humidity limitation: 10% - 80%.

## COMPATIBILITY

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### 【Biliary Plastic Stent Introducer】

Only applicable to Biliary Plastic Stent

Biliary Plastic Stent Introducer manufactured by Micro-Tech, see the matching matrix below:

Biliary Plastic Stent		Biliary Plastic Stent Introducer	
Diameter (Fr)	Shape	REF	Type
7Fr	For all shape (except double pigtails shape)	BPDI-0740/22	Normal
8.5Fr	For all shape	BPDI-0840/22	
10Fr	For all shape	BPDI-1040/22	
11.5Fr	For all shape	BPDI-1140/22	
7Fr	Only for double pigtails shape	BPDI-0700/18	Pusher

### 【Endoscopes】

#### For Biliary Plastic Stent and Biliary Plastic Stent Set

Working channel of Endoscope  $\geq 2.8\text{mm}$

### 【Guide wire】

#### For Biliary Plastic Stent and Biliary Plastic Stent Set

Guide wire length: 4.5m

Guide wire Diameter  $\leq 0.035''$

### **【X-ray machine】**

All the compatible devices which are legal listed in European Union is recommended.

## **DIRECTIONS FOR USE**

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### **【PREPARATIVE CHECK AND PREPARATION】**

1. Before using, inspect the pouch for any breach of the package. Do not use if package is damaged.
2. After verifying the sterilization expiry date, open the package carefully, take out the product.
3. If this device shows any sign of damage and suspicious problems, do not use. Do not attempt to repair nonfunctional or damaged devices.

### **【INSTRUCTIONS FOR USE】**

#### **Biliary Plastic Stent Set**

1. Perform routine ERCP to know property, position and extent of biliary lesions, and determine the desired plastic stent position;
2. Load positioning sleeve onto the plastic stent, and cover up flaps of the distal end (if any). If the distal end is pigtail, advance positioning sleeve along shaft of plastic stent to the distal end in order to straighten pigtail curl;

**Note: Tapered end of the plastic stent in bile duct is the distal end, and the other end of the plastic stent outside duodenal papilla is the proximal end.**

3. Thread plastic stent and sleeve onto the inner tube of the Biliary Plastic Stent Introducer. After the proximal end of the plastic stent reach the distal end of the outer tube of the Biliary Plastic Stent Introducer, thread the Biliary Plastic Stent Introducer onto the pre-positioned guide wire;
4. **For Pusher specification:** directly thread the plastic stent, sleeve and Biliary Plastic Stent Introducer onto the pre-positioned guide wire;
5. Fluoroscopically monitor guide wire distal position, confirm the guide wire distal end is above the stricture, stone, or injury, advance Biliary Plastic Stent Introducer over guide wire into working channel of endoscope;
6. Advance Biliary Plastic Stent Introducer in 1-2 cm increments until plastic stent is in desired position;
7. Fluoroscopically and endoscopically confirm desired plastic stent position;
8. After confirming plastic stent position, rotate and unlock rear handle, gently withdraw inner tube into outer tube by retracting rear handle while maintaining position of plastic stent, then remove Biliary Plastic Stent Introducer;
9. Gently remove guide wire from working channel of endoscope.

**NOTE: The Biliary Plastic Stent is MR Safe.**

## **PRODUCT DISPOSAL**

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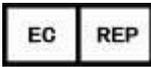
This product may be a potential biohazard after use. Handle and dispose of the product in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

## **POST-PROCEDURE**

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This device should not be left indwelling for more than 90 days, which should be removed via standard stent removal techniques by a trained physician in endoscopic biliary procedures. Please seek timely medical treatment in presence of uncomfortable symptoms.

## SYMBOL INDICATIONS

	Do not reuse		Do not resterilize
	Date of manufacture		Manufacturer
	Use by date		Caution
	Catalogue number		Batch code
	Authorized representative in the European Community		Sterilization using ethylene oxide
	Keep dry		Keep away from sunlight
	Consult instructions for use or consult electronic instructions for use		Do not use if package is damaged
	Sterile barrier system/ Sterile packaging		Open here
	Importer		Medical Device
	Unique device identifier		This device is not made with natural rubber latex
	Temperature limit: 10°C-25°C		Humidity limitation: 10%-80%
	Magnetic Resonance Safe		

**【Packaging】** Packed in flexible peel pouch

**【Production Date】** See packaging

**【Sterilization】** Sterilized by EO (ethylene oxide) gas

**【Period of Validity】** Two years

## **WARRANTY**

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Limited Warranty to Buyer. Micro-Tech warrants to Buyer that, for the earlier of one (1) year from the date of purchase, or until the product is used by Buyer, the products will be free from defects in materials and workmanship when stored and used in accordance with the instructions for storage and use provided by Micro-Tech and in accordance with applicable regulatory requirements. Descriptions or specifications appearing in Micro-Tech's literature are meant to generally describe the products and do not constitute any express warranties. Any technical advice with respect to the product and guarantee of specific properties of or in the products shall only be effective if and to the extent specifically confirmed by Micro-Tech in writing. These warranties shall not apply for product failure or deficiency due to improper storage, alteration, or the consequences of uses for which the products were not designed or that adversely affect the products' integrity, reliability, or performance.

## **Instruction page for Electronic instructions for use website**

To access the instructions for use, please go to <https://eifu.micro-tech.com.cn> by entering the product-specific IFU code BPDS03.

The hardware and software requirements to view / access IFUs are as follows:

- Both the computer or mobile devices (mobile phones, pad, notebooks and computer) can be used, with current operating system (computer: Apple's macOS system, Microsoft's Windows system; Mobile: Apple iOS system, Google Android system, HarmonyOS system).
- The browser must be the latest generation of Google Chrome, Firefox, Safari or Microsoft Edge.

For a paper copy, provided in 7 days at no cost, please call + 49(0)211 73 27 626-0

## CONTACTS



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