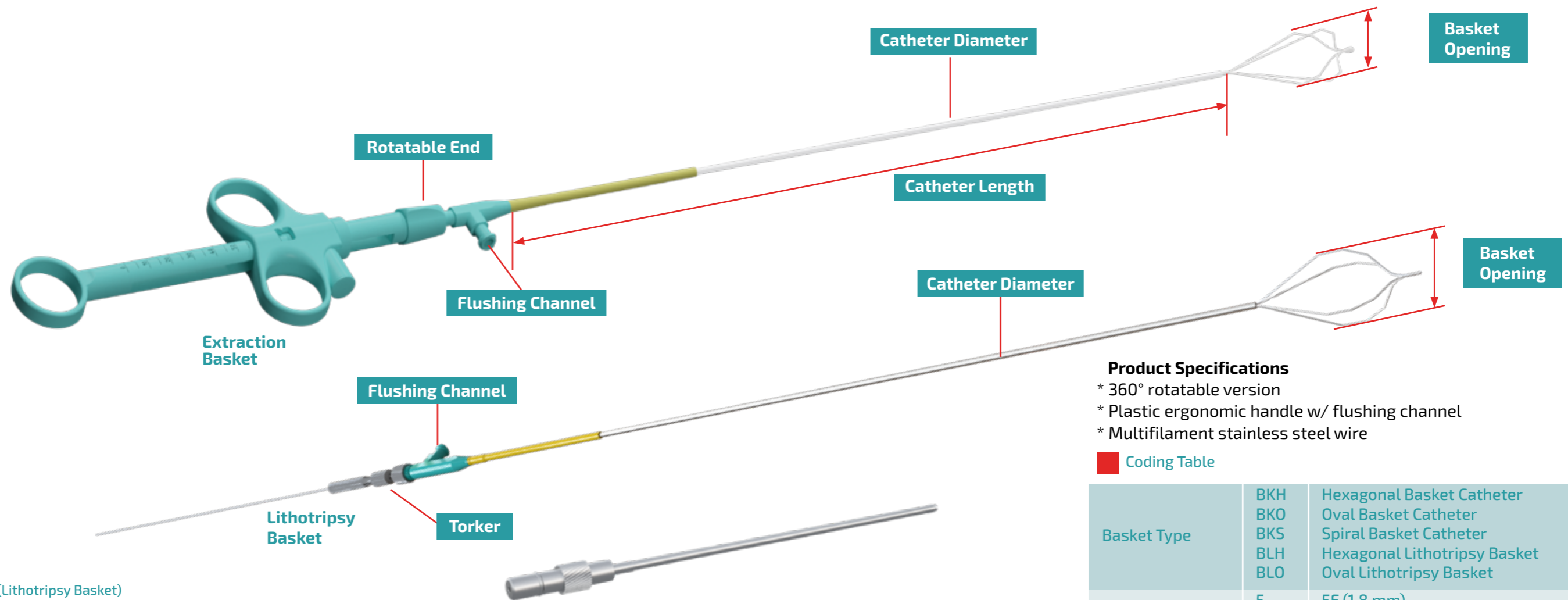


## EXTRACTION BASKET

■ Size Table (Extraction Basket)

Catheter Diameter	5F	7F	5F	7F	5F	7F	5F	7F	5F	7F	5F	7F
Catheter Length/ Basket Opening	10		15		20		25		30		35	
120	✓	X	✓	X	✓	X	✓	X	X	X	X	X
180	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	X	✓
215	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	X	✓
230	X	X	X	X	X	✓	✓	✓	X	✓	X	✓
250	X	X	X	X	X	X	X	✓	X	✓	X	✓



**Product Specifications**

- \* 360° rotatable version
- \* Plastic ergonomic handle w/ flushing channel
- \* Multifilament stainless steel wire

■ Coding Table

Basket Type	BKH BKO BKS BLH BLO	Hexagonal Basket Catheter Oval Basket Catheter Spiral Basket Catheter Hexagonal Lithotripsy Basket Oval Lithotripsy Basket
Catheter Diameter	5 7	5F (1,8 mm) 7F (2,3 mm)
Basket Opening	10 15 20 25 30 35	10 mm 15 mm 20 mm 25 mm 30 mm 35 mm
Catheter Length	12 18 21 23 25 20/40	120 cm 180 cm 215 cm 230 cm 250 cm 200/400 cm
Handle Feature	SU SY RD RY	Fixed End Fixed End Flushing Channel Rotatable Rotatable Flushing Channel

■ Size Table (Lithotripsy Basket)

Catheter Diameter	7F			
Catheter Length/ Basket Opening	20	25	30	35
200/400	✓	✓	✓	✓

**Lithotripter Spring (Reusable)**

■ Size Table (Lithotripter Spring)

Spring Type	MS	Metal Spring
Spring Diameter	26	2.6 mm
Spring Length	18	180 cm
	20	200 cm



**Coding**

**BKH** 5 20 12 **RY**  
1 2 3 4 5

- 1- **BKH** : Basket Type
- 2- **5** : Catheter Diameter
- 3- **20** : Basket Opening
- 4- **12** : Catheter Length
- 5- **SU** : Handle Feature

**BKS**

**BKH**

**BKO**

## POLYPECTOMY SNARE

Size Table (Asymmetric)

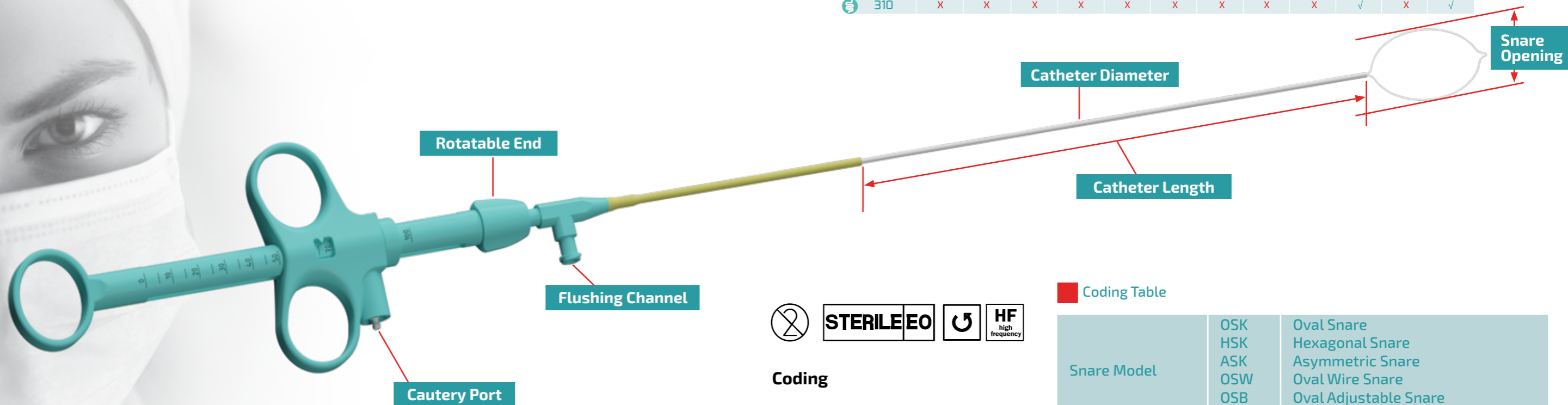
Catheter Diameter	5F	7F	5F	7F	5F	7F
Catheter Length/ Snare Opening	20		25		30	
120	✓	X	✓	X	X	X
180	✓	✓	✓	✓	X	✓
215	X	X	X	X	X	X
230	✓	✓	✓	✓	X	✓
310	X	X	X	✓	X	✓

Size Table (Adjustable)

Catheter Diameter	5F	7F
Catheter Length/ Snare Opening	20-30	
120	X	X
180	X	✓
215	X	X
230	X	✓
250	X	✓
310	X	X

Size Table (Oval, Hexagonal)

Catheter Diameter	5F	7F	5F	7F	5F	7F	5F	7F	5F	7F	5F	7F
Catheter Length/ Snare Opening	10		15		20		25		30		35	
120	✓	X	✓	X	✓	X	✓	X	X	X	X	X
180	X	✓	✓	✓	✓	✓	✓	✓	X	✓	X	✓
215	X	X	X	X	X	X	X	X	X	X	X	X
230	X	✓	✓	✓	✓	✓	✓	✓	X	✓	X	✓
250	✓	✓	✓	✓	X	✓	X	✓	X	✓	X	✓
310	X	X	X	X	X	X	X	X	X	✓	X	✓



**Coding**

OSK 5 20 12 RY  
1 2 3 4 5

- 1- **OSK**: Snare Model
- 2- **5** : Catheter Diameter
- 3- **20** : Snare Opening
- 4- **12** : Catheter Length
- 5- **RY** : Handle Feature

**Product Specifications**

- \* 360° rotatable version with leveling feature
- \* Plastic ergonomic handle w/ flushing channel
- \* Multifilament stainless steel wire

Coding Table

Snare Model	OSK HSK ASK OSW OSB OSWB	Oval Snare Hexagonal Snare Asymmetric Snare Oval Wire Snare Oval Adjustable Snare Oval Wire Adjustable Snare
Catheter Diameter	5 7	5F (1,8 mm) 7F (2,3 mm)
Snare Opening	10 15 20 25 30 35 20/30	10 mm 15 mm 20 mm 25 mm 30 mm 35 mm Adjustable Between 20-30 mm
Catheter Length	12 18 21 23 25 31	120 cm 180 cm 215 cm 230 cm 250 cm (enteroscopy) 310 cm (enteroscopy)
Handle Feature	SU SY RD RY	Fixed End Fixed End Flushing Channel Rotatable Rotatable Flushing Channel

HSK

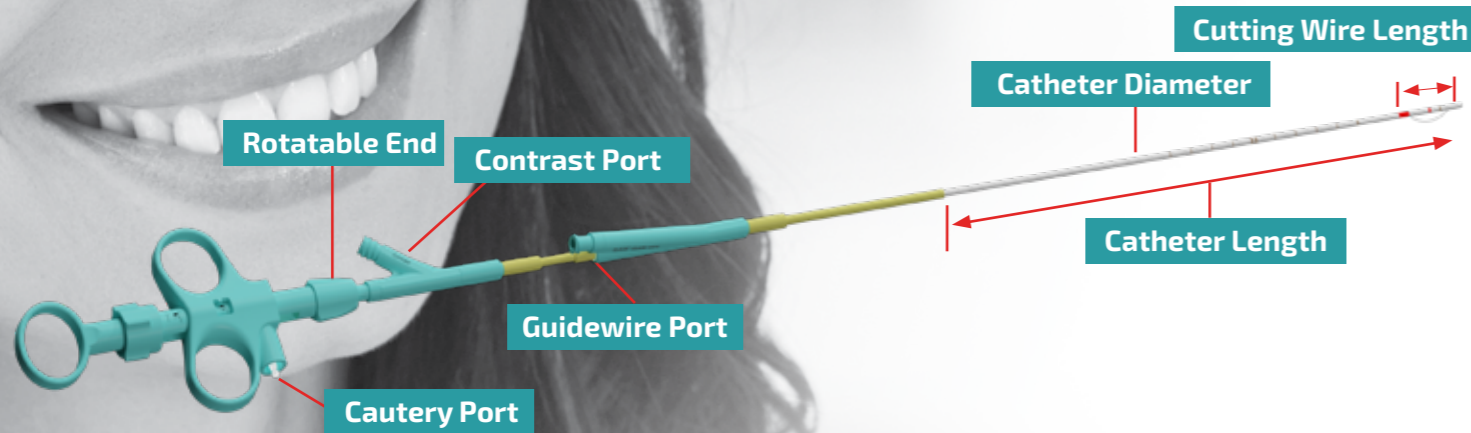
OSK

ASK

OSB

OSWB

## SPHINCTEROTOME



### Coding Table

Sphincterotome Model	PK PPK IPK RPK NPK KPK	Standard Precut Isolated Rotatable Isolated Needle Tip Knife Tip
Catheter Diameter	5/4 5 7 7/4 7/5 8/5 8/6	Reduced from 5F to 4F 5F 7F Reduced from 7F to 4F Reduced from 7F to 5F Reduced from 8F to 5F Reduced from 8F to 6F
Catheter Type	1L 2L 3L	Single-Lumen Double-Lumen Triple-Lumen
Cutting Wire Length	20 25 30 0/6 0/10	20 mm 25 mm 30 mm 0-6 mm Adjustable Needle Tip 0-10 mm Adjustable Knife Tip
Catheter Length	18 20 21 23	180 cm 200 cm 215 cm 230 cm
Guidewire Diameter	25 35	0,025" 0,035"
Cutting Wire Type	R W K	Rope Wire Knife
Catheter Tip Type	T D	Tapered Dome

### Size Table (Needle Tip/Knife Tip)

Model	1 Lumen (Knife Tip)			1 Lumen (Needle Tip)			2 Lumen (Needle Tip)			3 Lumen (Needle Tip)			
	Catheter Diameter	5F	7F	7/5F	5F	7F	7/5F	5F	7F	7/5F	5F	7F	7/5F
Catheter Length/ Cutting Wire Length	0/10			0/6			0/6			0/6			
180	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	✓
200	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	✓
215	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	✓
230	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	✓

### Size Table (2 Lumen)

Catheter Diameter	5/4F	5F	7F	7/4F	7/5F	5/4F	5F	7F	7/4F	7/5F	5/4F	5F	7F	7/4F	7/5F
Catheter Length/ Cutting Wire Length	20					25					30				
215	X	✓	✓	✓	✓	X	✓	✓	✓	✓	X	✓	✓	✓	✓

### Size Table (3 Lumen)

Catheter Diameter	7F	7/4F	7/5F	8/5F	8/6F	7F	7/4F	7/5F	8/5F	8/6F	7F	7/4F	7/5F	8/5F	8/6F
Catheter Length/ Cutting Wire Length	20					25					30				
180	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
215	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
230	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

### Size Table (Isolated 2 Lumen)

Catheter Diameter	7F	7/4F	7/5F	7F	7/4F	7/5F	7F	7/4F	7/5F
Catheter Length/ Cutting Wire Length	20			25			30		
215	✓	✓	✓	✓	✓	✓	✓	✓	✓
230	✓	✓	✓	✓	✓	✓	✓	✓	✓

### Size Table (Isolated 3 Lumen)

Catheter Diameter	7F	7/4F	7/5F	7F	7/4F	7/5F	7F	7/4F	7/5F
Catheter Length/ Cutting Wire Length	20			25			30		
215	✓	X	✓	✓	X	✓	✓	X	✓
230	✓	X	✓	✓	X	✓	✓	X	✓

### Size Table (Rotatable 2 ve 3 Lumen)

Catheter Diameter	7F	7/4F	7/5F	7F	7/4F	7/5F	7F	7/4F	7/5F
Catheter Length/ Cutting Wire Length	20			25			30		
180	✓	✓	✓	✓	✓	✓	✓	✓	✓
215	✓	✓	✓	✓	✓	✓	✓	✓	✓
230	✓	✓	✓	✓	✓	✓	✓	✓	✓



PK (TAPERED TIP)

PK (DOME TIP)

PPK

IPK (ISOLATED)

NEEDLE TIP

KNIFE TIP



### Coding

PK 7/5 3L 25 21 35 R T  
1 2 3 4 5 6 7 8

- 1- PK : Sphincterotome Model
- 2- 7/5: Catheter Diameter
- 3- 3L : Catheter Type
- 4- 25 : Cutting Wire Length
- 5- 21 : Catheter Length
- 6- 35 : Guidewire Diameter
- 7- R : Cutting Wire Type
- 8- T : Catheter Tip Type

### Product Specifications

- \* 360° rotatable version
- \* Plastic ergonomic handle w/ flushing channel
- \* Multifilament stainless steel wire

# BILIARY STENT

# PANCREATIC STENT

NEW

Size Table(Biliary Stent)

Stent Diameter	5F		7F		8,5F		10F		11F	
	BS	BSP	BS	BSP	BS	BSP	BS	BSP	BS	BSP
5 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
6 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
7 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
8 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
10 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
11 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
12 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
13 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
14 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
15 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
16 cm	x	x	✓	x	✓	x	✓	x	✓	x
17 cm	x	x	✓	x	✓	x	✓	x	✓	x
18 cm	x	x	✓	x	✓	x	✓	x	✓	x
19 cm	x	x	✓	x	✓	x	✓	x	✓	x
20 cm	x	x	✓	x	✓	x	✓	x	✓	x
21 cm	x	x	✓	x	✓	x	✓	x	✓	x
22 cm	x	x	✓	x	✓	x	✓	x	✓	x

Size Table(Pancreatic Stent)

Stent Diameter	5F	7F	10F
Stent Length/ Stent Type	PS	PS	PS
2 cm	✓	x	x
3 cm	✓	✓	✓
4 cm	✓	✓	✓
5 cm	✓	✓	✓
6 cm	✓	✓	✓
7 cm	✓	✓	✓
8 cm	✓	✓	✓
9 cm	✓	✓	✓
10 cm	✓	✓	✓
11 cm	✓	✓	✓
12 cm	✓	✓	✓
13 cm	✓	✓	✓
14 cm	✓	✓	✓
15 cm	✓	✓	✓
16 cm	x	✓	✓
17 cm	x	✓	✓
18 cm	x	✓	✓

Coding Table

Stent Type	BS BSP	Biliary Stent Biliary Stent w/markerband
Stent Diameter	5	5F (1,8 mm)
	7	7F (2,3 mm)
	8,5	8,5F (2,8 mm)
	10	10F (3,3 mm)
	11,5	11,5F (3,8 mm)
Stent Length	5	5 cm
	6	6 cm
	7	7 cm
	8	8 cm
	9	9 cm
	10	10 cm
	11	11 cm
	12	12 cm
	13	13 cm
	14	14 cm
	15	15 cm
	16	16 cm
	17	17 cm
	18	18 cm
19	19 cm	
20	20 cm	
21	21 cm	
22	22 cm	
Stent Model	C	Curved

Curved



Coding

BS	5	7	C
1	2	3	4

- 1- **BS** : Stent Type
- 2- **5** : Stent Diameter
- 3- **7** : Stent Length
- 4- **C** : Stent Model

**Product Specifications**

- \* High fluidity
- \* PTFE material with good radiopacity and nonstick surface
- \* Optional metal radiopaque markers



Coding Table

Stent Type	PS	Pancreatic Stent
Stent Diameter	5	5F
	7	7F
	10	10F
Stent Length	2	2 cm
	3	3 cm
	4	4 cm
	5	5 cm
	6	6 cm
	7	7 cm
	8	8 cm
	9	9 cm
	10	10 cm
	11	11 cm
	12	12 cm
	13	13 cm
	14	14 cm
	15	15 cm
16	16 cm	
17	17 cm	
18	18 cm	
Flap Number	S	One Flap Two Flap



Coding

PS	5	10	S
1	2	3	4

- 1- **PS** : Stent Type
- 2- **5** : Stent Diameter
- 3- **10** : Stent Length
- 4- **S** : Flap Number

**Product Specifications**

- \* High fluidity
- \* PTFE material with good radiopacity and nonstick surface

# BILIARY STENT SET

NEW

## Stent Pusher



### Size Table

Pusher Length	5F P	7F P
180 cm	✓	✓

## Stent Pusher and Delivery Catheter



### Size Table

Set Length	8.5F PG	10F PG	11.5F PG
180/210cm	✓	✓	✓

### Coding Table

Stent Set Model	P PBS PG PG BS	Stent Pusher Stent Pusher and Biliary Stent Pusher and Delivery Catheter Biliary Stent Set
Stent Set Diameter	5 7 8 10 11.5	5F 7F 8,5F 10F 11,5F
Stent Set Length	18 18/21	180 cm 180/210 cm
Biliary Stent Length	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	5 cm 6 cm 7 cm 8 cm 9 cm 10 cm 11 cm 12 cm 13 cm 14 cm 15 cm 16 cm 17 cm 18 cm 19 cm 20 cm 21 cm 22 cm
Stent Model	C	Curved



### Coding

PG BS	10	18/21	10	C
1	2	3	4	5

- 1- **PG BS** : Biliary Stent Set
- 2- **10** : Stent Diameter
- 3- **18/21** : Stent Set Length
- 4- **10** : Stent Length
- 5- **C** : Stent Model

### Product Specifications

- \* High fluidity
- \* PTFE Catheter with nonstick surface
- \* Radiopaque Markers

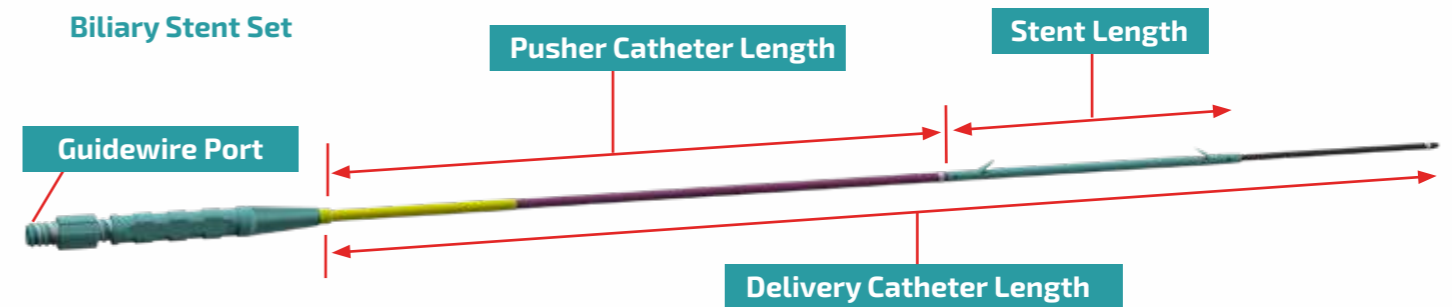
## Stent Pusher and Biliary Stent



### Size Table

Pusher Length	Stent Length	5F P BS	7F P BS
180 cm	5 cm	✓	✓
180 cm	6 cm	✓	✓
180 cm	7 cm	✓	✓
180 cm	8 cm	✓	✓
180 cm	9 cm	✓	✓
180 cm	10 cm	✓	✓
180 cm	11 cm	✓	✓
180 cm	12 cm	✓	✓
180 cm	13 cm	✓	✓
180 cm	14 cm	✓	✓
180 cm	15 cm	✓	✓
180 cm	16 cm	X	✓
180 cm	17 cm	X	✓
180 cm	18 cm	X	✓
180 cm	19 cm	X	✓
180 cm	20 cm	X	✓
180 cm	21 cm	X	✓
180 cm	22 cm	X	✓

## Biliary Stent Set



### Size Table

Set Length	Stent Length	8.5F PG BS	10F PG BS	11.5F PG BS
180/210cm	5 cm	✓	✓	✓
180/210cm	6 cm	✓	✓	✓
180/210cm	7 cm	✓	✓	✓
180/210cm	8 cm	✓	✓	✓
180/210cm	9 cm	✓	✓	✓
180/210cm	10 cm	✓	✓	✓
180/210cm	11 cm	✓	✓	✓
180/210cm	12 cm	✓	✓	✓
180/210cm	13 cm	✓	✓	✓
180/210cm	14 cm	✓	✓	✓
180/210cm	15 cm	✓	✓	✓
180/210cm	16 cm	✓	✓	✓
180/210cm	17 cm	✓	✓	✓
180/210cm	18 cm	✓	✓	✓
180/210cm	19 cm	✓	✓	✓
180/210cm	20 cm	✓	✓	✓
180/210cm	21 cm	✓	✓	✓
180/210cm	22 cm	✓	✓	✓



# C E R T I F I C A T E

## Full Quality Assurance System

### Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : Technocast Otomotiv San ve Tic. A.Ş.

Company Address : Organize Sanayi Bölgesi Gazi Osman Paşa Mah. 6. Cad. No:12  
Çerkezköy TEKİRDAĞ / TURKEY

Manufacturing Site : Technocast Otomotiv Sanayi ve Ticaret A.Ş. Medikal Şubesi  
Çerkezköy Organize San. Bölg. Gazi Osman Paşa Mah. 6. Cad. No:26  
Çerkezköy TEKİRDAĞ / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)

Product : - Extraction Basket - Class IIa - Sterile  
- Grasping Forceps - Class IIa - Sterile  
- Sphincterotome - Class IIb - Sterile  
- Polypectomy Snare - Class IIb - Sterile  
- E.R.C.P Catheter - Class Is - Sterile  
- Stone Extraction Balloon - Class IIa - Sterile  
- Biliary Stent - Class IIa - Sterile

GMDN : 37141, 37141, 58039, 38827, 16429, 46715, 10696

Certificate Number : M.2016.106.7002

Report Number : MD.3157.YB

Initial Assessment Date : 27.07.2016

Registration Date : 04.10.2016

Recertification Assessment Date : 04.03.2020

Reissue Date / No : 10.06.2020/01

Revision Date /No : -

Expiry Date : 27.05.2024



UDEM International Certification  
Auditing Training Centre Industry  
and Trade Inc. Co.



UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design-examination certificate is required for placing the Class II devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through [www.udem.com.tr](http://www.udem.com.tr).

**Address:** Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY

**Phone:** +90 0312 443 03 90 **Fax:** +90 0312 443 03 76

**E-mail:** [info@udemltd.com.tr](mailto:info@udemltd.com.tr) [www.udem.com.tr](http://www.udem.com.tr)



# EC CERTIFICATE

## Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : Technocast Otomotiv San ve Tic. A.Ş.

Company Address : Organize Sanayi Bölgesi Gazi Osman Paşa Mah. 6. Cad. No:12  
Çerkezköy TEKİRDAĞ / TURKEY

Üretim Adresi : Technocast Otomotiv San ve Tic. A.Ş Medikal Şubesi  
Çerkezköy Organize San. Bölg. Gazi Osman Paşa Mah. 6. Cad.  
No:26 Çerkezköy TEKİRDAĞ/ TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)

Product : Sclerotherapy Needle - Class IIa - Sterile  
Pancreatic Stent - Class IIa - Sterile  
Stent Pusher - Class Is - Sterile  
Stent Pusher and Delivery Catheter - Class Is - Sterile  
Stent Pusher and Biliary Stent - Class IIa - Sterile  
Biliary Stent Set - Class IIa - Sterile

GMDN : 38825, 42701, 46689, 46689, 46689, 46689

Certificate Number : M.2021.106.14330

Report Number : MD.3157.IB

Initial Assessment Date : 05.01.2021

Registration Date : 19.03.2021

Revision Date /No : -

Expiry Date : 27.05.2024



UDEM International Certification  
Auditing Training Centre Industry  
and Trade Inc. Co.



UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned

**Address:** Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY  
**Phone:** +90 0312 443 03 90 **Fax:** +90 0312 443 03 76  
**E-mail:** info@udemltd.com.tr www.udem.com.tr