

# Advanced Therapeutics

# 02

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For time-efficient and safe procedures.

PENTAX Medical ESD accessories are innovative, easy to handle and highly controllable for any kind of dissection of the entire GI tract.

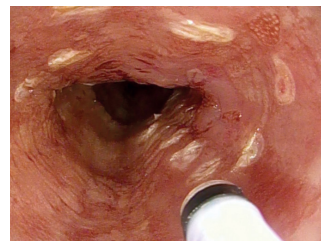
A full range of ESD accessories for a complete dissection.

PENTAX Medical accessories cover all steps of the ESD procedure and can be perfectly combined with the PENTAX Medical RetroView scope, with its unique 210° deflection ability and reduced bending radius of its distal end, for a safe and time-efficient dissection.

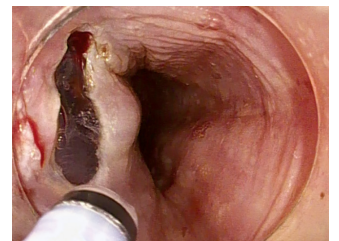
### **Marking, marginal incision, dissection and hemostasis with Splash M-Knife**

Splash M-Knife is a unique multi-functional accessory allowing complete ESD procedures with a single device.

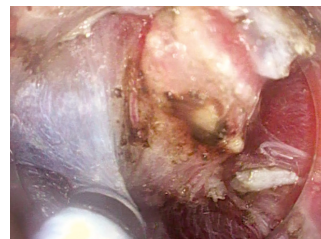
It has been developed and designed to achieve clear marking, better hemostasis and smoother and easier operation with fixed knife length and hooking mechanism. Splash M-Knife is designed to improve hemostasis ability with better bleeding control during a procedure without replacing the knife.



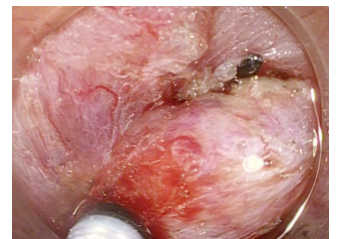
Marking



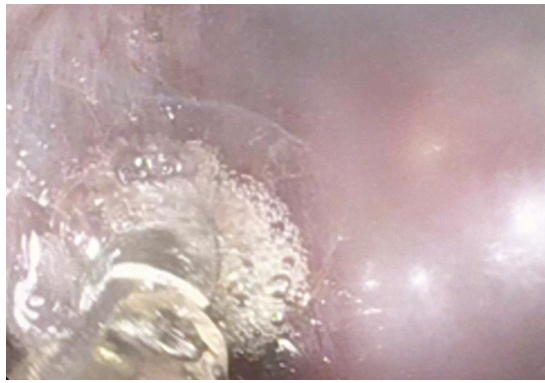
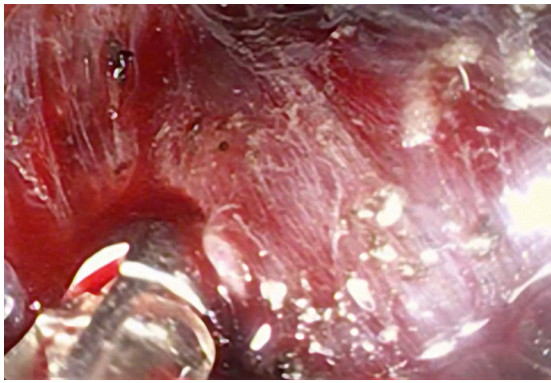
Resection



Dissection



Hemostasis



## Hemostasis with the bipolar HemoStat WideCup

The HemoStat WideCup is used to accomplish effective initial hemostasis for gastrointestinal bleeding.

The bipolar forceps device is designed to support fast and efficient hemostasis without causing damage to the deeper tissue through thermal degeneration. The HemoStat WideCup is expected to aid prevention of re-bleeding, especially during ESD.\*<sup>1</sup>

<sup>\*1</sup> M Kataoka et al. "Clinical evaluation of emergency endoscopic hemostasis with bipolar forceps in non-variceal upper gastrointestinal bleeding" *Digestive Endoscopy* (2010) 22, 151-155



## Dissection with Mucosectom

With its innovative design, Mucosectom overcomes the challenges of dissection procedures safely and efficiently.

The insulated tip can reduce the risk of perforation, while the extended knife length can reduce the amount of time the procedure takes.\*<sup>2</sup> The knife on the side of the 360° rotatable tip and the optical marker are designed to assist the physician in holding the accessory in the direction of the lesion and dissecting it precisely.

<sup>\*2</sup> Hiromitsu Kanzaki MD1, Ryu Ishihara MD1, Takashi Ohta MD1, Kengo Nagai MD1, Fumi Matsui MD1, Takeshi Yamashina MD1, Masao Hanafusa MD1, Sachiko Yamamoto MD1, Noboru Hanaoka MD1, Yoji Takeuchi MD1, Koji Higashino MD1, Noriya Uedo MD1, Hiroyasu Iishi MD1 and Masaharu Tatsuta MD1 "Randomized Study of Two Endo-knives for Endoscopic Submucosal Dissection of Esophageal Cancer" *The American Journal of Gastroenterology* 2013 Aug;108(8):1293-8. doi: 10.1038/ajg.2013.161. Epub 2013 Jun 4

# PENTAX Medical ESD – precise, efficient and safe.

## Splash M-Knife: Multi-functional device for a complete ESD



- Disk in the knife helps to hook up the tissue for improved safety and ease of cutting
- Metal plate that closes the knife for clear marking and better hemostasis
- Water jet function that enables additional injection without changing the device

\*3 Major bleeding needs to be stopped by a clip or hemostasis forceps such as HemoStat WideCup

INNOVATIVE  
DESIGN



## Mucosectom: For a safe and fast therapeutic approach



- Insulated tip and single-sided knife designed for a safer dissection
- Rotatable tip with optical marker supports a precisely directed dissection
- Extended knife length designed for a faster procedure\*4

\*4 Kawahara Y, Imagawa A, Fujiki S, Shiratori Y. "Novel procedure of endoscopic submucosal dissection (ESD) using a new device (mucosectome) for early esophageal cancer" *Gastrointest Endosc.* 2006;63:AB222

INNOVATIVE  
DESIGN



## Ksnare: All-in-one



- Enables hybrid techniques EMR/ESD especially in the colon
- Combines an adjustable knife on the tip designed for precise marking and incision, and a snare for resection
- The all-in-one accessory for supporting a complete lesion resection



## Bipolar HemoStat WideCup: Easy control of bleeding

BIPOLAR INNOVATIVE DESIGN



- Bipolar HemoStat WideCup reduces the impact of deeper tissue thermal degeneration\*<sup>5</sup>
- Supports prevention of re-bleeding\*<sup>6</sup>
- Based on its flexibility, it can be used for various applications such as EMR/ESD, gastrointestinal bleeding and papilla resection

\*<sup>5</sup> Compared with monopolar forceps

\*<sup>6</sup> M Kataoka et al. "Clinical evaluation of emergency endoscopic hemostasis with bipolar forceps in non-variceal upper gastrointestinal bleeding" *Digestive Endoscopy* (2010) 22, 151-155



	Model name	Item number	Working Length [mm]	Min. Channel [mm]	Max. Insertion Portion Width [mm]	Knife Length [mm]	Adjustable Knife Length [mm]	Snare/Cup Opening [mm]	Packaging	
									Single unit	Boxes of 5
<b>Splash M-Knife</b>	DN-D2718B	80387	1,800	2.8	2.7	Extended 2.0			X	
						Retracted 0.5			X	
	DN-D2722B	80396	2,200	2.8	2.7	Extended 2.0			X	
						Retracted 0.5			X	
<b>Mucosectom</b>	DP-D2518	47662	1,800	2.8	2.5	5.0			X	
	DP-D2622	47902	2,200	2.8	2.6	2.5			X	
<b>Ksnare</b>	DO-D2618	47905	1,800	2.8	2.6	6.0	2.0-6.0	22	X	
	DO-D2622	47908	2,200	2.8	2.6	6.0	2.0-6.0	22	X	
<b>HemoStat WideCup*<sup>7</sup></b>	HS-D2618	80942	1,800	2.8	2.6			5.8		X
	HS-D2622	80940	2,200	2.8	2.6			5.8		X

\*<sup>7</sup> Equipped with active cord and plug

Consult your local representative for information on the products currently available in your region.

# TOP ENDOSCOPIC HOOD

The slit and hole allows quick fluid outlet from the hood.



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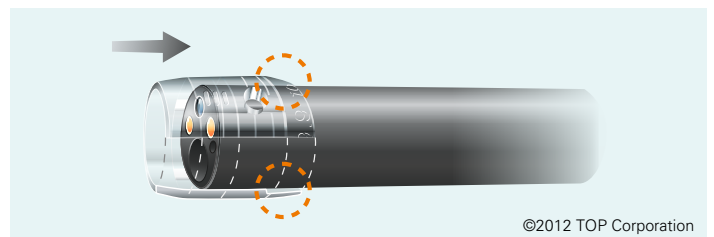
## Slit and Hole

Fluid in the hood is discharged by capillarity and pressure difference.

## How to use

### 1. Attachment direction

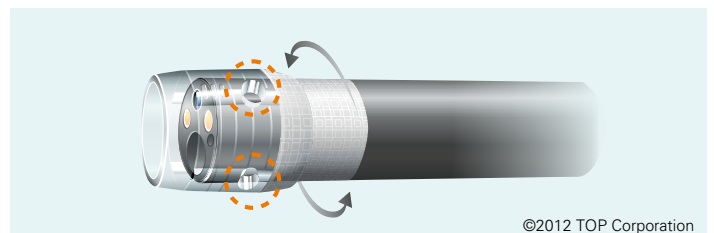
Attach the hood to the scope in the direction shown by the arrow. Avoid attaching upside down. The attachment side is thinner, with matching endoscope diameter indicated.



©2012 TOP Corporation

### 2. Securing with tape

Secure the loose attachment (e.g. unstable hood) with tape. Avoid covering the side hole with the tape.



©2012 TOP Corporation

Lubricant jelly may clog the side hole, preventing fluid outlet.

## Straight type



Model name	Item number	Compliant endoscope O.D.	Drainage function	Packaging unit
SS	306030	8.6~9.8 mm	Off	5pcs./box
SL	306031	10.6~12.6 mm		

## Slit and Hole type



Model name	Item number	Compliant endoscope O.D.	Drainage function	Packaging unit
SHLL-B	306032	12.6~14.0 mm	On	5pcs./box

## Slit and Hole F(Focus) type



Model name	Item number	Compliant endoscope O.D.	Hood protrusion length	Drainage function	Packaging unit
SHF-010	306025	9.0~9.2 mm	3.5~7.0 mm	On	5pcs./box
SHF-025	306026	9.8~9.9 mm			
SHF-030	306027	9.9~10.5 mm			
SHF-035	306028	10.8 mm			
SHF-050	306033	11.7~12.2 mm			
SHF-055	306034	12.8 mm			
SHF-060	306029	13.2 mm			

Manufactured by   
TOP Corporation

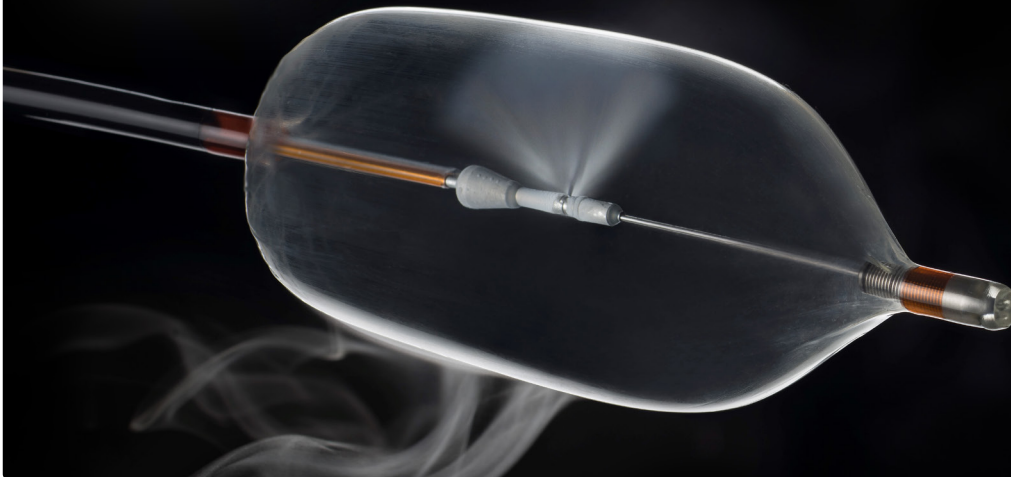
Ask your local sales representative about compatibility with the PENTAX Medical endoscopes. In order to select the compatible TOP Hood for your endoscope, please consider that variation of the nominal scope size may occur after service and repair. Some of the above products may not be available in all countries. Please consult your local representative for further information.



# The C2 CryoBalloon™ Ablation System

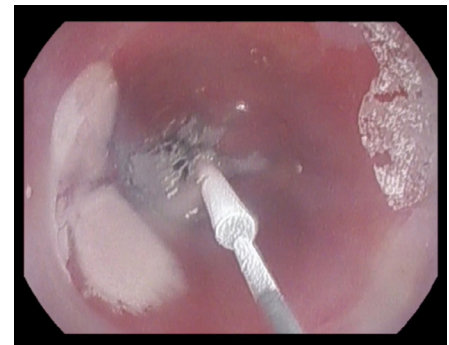
For the Endoscopic Cryoablation of Barrett's Esophagus\*

\*Cleared in US, Europe and Canada



C2 CryoBalloon™ Ablation System has not been commercially released in all European countries. Please contact your local sales rep to learn more.

The C2 CryoBalloon™ Ablation System is used to destroy diseased/unwanted tissue by applying extreme cold. A balloon catheter is positioned in the area of the diseased tissue and the compliant balloon is then inflated to contact the esophageal wall circumferentially. The diffuser, within the expanded balloon, is then guided for ablation by pointing the diffuser outlet to deliver nitrous oxide directly at the targeted tissue. The extreme cold eradicates the targeted precancerous or abnormal lesions by a cryogenic heat transfer process between the balloon and the esophageal lining delivering a controlled therapy ablating only the targeted lesions. The system allows physicians complete control of the procedure with direct visualization of the treatment area during the procedure, which lasts between 15 to 30 minutes.[1],[2]

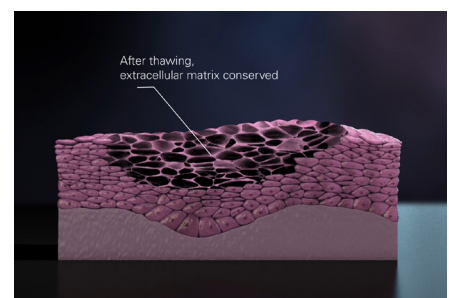
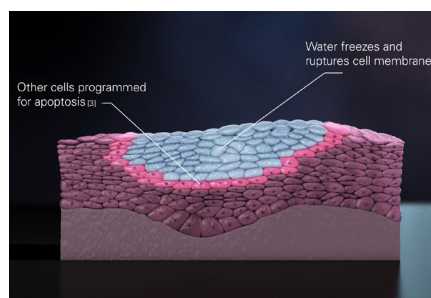
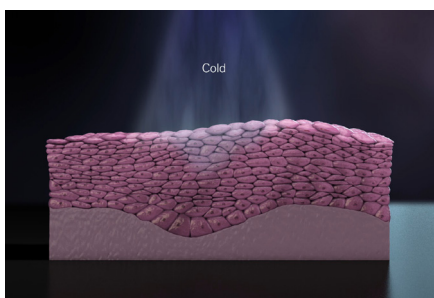


Circumferential ablation of the gastroesophageal junction. Courtesy of Dr. Haidry, University College Hospital, London

[1] Canto MI, Shaheen NJ, Almario JA, Voltaggio L, Montgomery E, Lightdale CJ. Multifocal Nitrous Oxide Cryoballoon Ablation with or without EMR for Treatment of Neoplastic Barrett's Esophagus. *Gastrointest Endosc.* 2018 Apr 4; pii: S0016-5107(18)30259-1. doi: 10.1016/j.gie.2018.03.024. PMID: 29626424

[2] Künzli HT, Schölvinck DW, Meijer SL, Seldenrijk KA, Bergman JGHM, Weusten BLAM. Efficacy of the CryoBalloon Focal Ablation System for the Eradication of Dysplastic Barrett's Esophagus Islands. *Endoscopy.* 2017 Feb;49(2): 169-175. doi: 10.1055/s-0042-120117. Epub 2016 Dec 20. PMID: 27997963

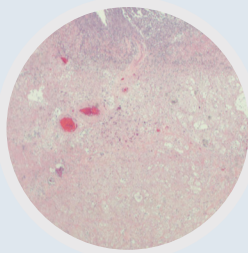
## How does the cryoablation work?



[3] Baust, J.G; Gage, A.A; Bieklund Johansen, T.E and Baust, J.M. Mechanisms of Cryoablation: Clinical Consequences on Malignant Tumors; *Cryobiology.* 2014 Feb. 68(1): 1-11

The new C2 CryoBalloon™ Ablation System offers several key advantages including the ability to ablate a wide range of patients, enhanced visualization and control as the ablation catheter is deployed through the working channel of the endoscope. “With the C2 CryoBalloon™ Ablation System, you can promote your practice as a more comprehensive Barrett’s center with the latest and best treatment options,” said Harshit S. Khara, MD, FACP, FASGE, Clinical Associate Professor of Medicine, Geisinger Medical Center.

### Ablation extending to the submucosa<sup>1</sup>



Combines deep ablation with a favorable safety profile<sup>2</sup>

1. Louie B, et al, Evaluation of a Novel Swipe Cryoballoon Ablation System in Bench, Porcine, and Human Esophagus Models. *Gastrointestinal Endoscopy*, Volume 85, No. 5S, AB513-AB514: 2017.

2. Schölvinck DW, et al, Balloon-Based Esophageal Cryoablation with a Novel Focal Ablation Device: Dose-Finding and Safety in Porcine and Human Models. *Diseases of the Esophagus*, 2017 Nov 1;30(11):1-8.

### Effective Endoscopic Treatment For BE-Associated Neoplasia<sup>3</sup>

95%

Complete Eradication of Dysplasia

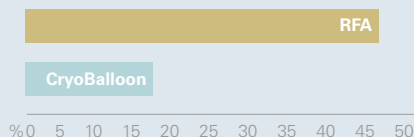
88%

Complete Eradication of Intestinal Metaplasia

3. Canto M, et al. Multifocal Nitrous Oxide Cryoballoon Ablation With or Without EMR for Treatment of Neoplastic Barrett’s Esophagus. *Gastrointest Endosc*. 2018 2018; 88: 438-446. doi: 10.1016/j.gie.2018.03.024

### Less Pain<sup>4</sup>

PATIENTS REPORTING SEVERE PAIN AT DAY 2



4. Van Munster, et al, Post-Procedural Pain After Endoscopic Ablation Therapy of Barrett’s Esophagus: Is Cryo Ablation Less Painful Compared with Radiofrequency Ablation?, *Gastrointestinal Endoscopy*. 2017 May; Volume 85, Issue 5, Supplement, Page AB568.

## All in a Smart and Compact Design

C2 CryoBalloon™ Ablation System Provides:

- Targeted access delivered through the working channel of a therapeutic endoscope
- An intuitive interface
- Smart, compact design that eliminates the need for large tanks or capital equipment



## C2 CryoBalloon™ Ablation System portfolio of products

Multiple CryoBalloon shapes and targeting options designed for various anatomic structures

### Pear shaped catheter



Model name	Article number	Pack size	Description
FG-1024	300617	1	Pear shaped catheter designed for Ablation of GEJ

### Standard shaped catheter



Model name	Article number	Pack size	Description
FG-1028	300613	1	Standard shaped catheter for tubular esophagus

### C2 CryoBalloon™ Ablation System controller and cartridges



Model name	Article number	Pack size	Description
FG-1017	300610	1	C2 CryoBalloon™ Ablation System Controller
FG-1013	300612	5	C2 CryoBalloon™ Ablation System Cartridge

### C2 CryoBalloon™ Ablation System Foot Pedal




Model name	Article number	Pack size	Description
FG-1018	300611	1	C2 CryoBalloon™ Ablation System Foot Pedal, enables rotational & axial targeting

#### Manufacturers


**Splash M-Knife**  
**Mucosectom**  
**Ksnare**  
**HemoStat WideCup**


 **HOYA Corporation**  
6-10-1, Nishi-shinjuku  
Shinjuku-ku, Tokyo  
160-0023 Japan

**TOP Endoscopic Hood**

 **TOP Corporation**  
19-10, Senju Nakai-cho  
Adachi-ku, Tokyo  
120-0035 Japan


**C2 CryoBalloon™**  
**Ablation**  
**System**

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USA

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Julius-Vosseler-Straße 104  
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


TÜV SÜD CE 0123 Medical Device Class: IIb

 MPS Medical Product Service GmbH  
Borngasse 20  
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TÜV SÜD CE 0123 Medical Device Class: IIa

 PENTAX Europe GmbH  
Julius-Vosseler-Straße 104  
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TÜV Rheinland CE 0197 Medical Device Class: IIa

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This product must be used only by healthcare professionals.

Before usage and for detailed product specifications, please refer to the instructions for use. In the interest of technical process, specifications may change without notice.

Product availability cannot be guaranteed in all countries. For further information please contact your local sales representative.

**PENTAX**  
**MEDICAL**